

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) May 17, 2018
)
Doris Jones, an individual,)
)
Plaintiff,)
) CV-16-00782-PHX-DGC
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
)
Defendants.)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 3 - A.M. SESSION

(Pages 469 - 590)

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EXAMINATIONWITNESSPAGE

DAVID GARCIA, M.D.

Direct Examination By Mr. Clark

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Cross-Examination By Mr. North

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Redirect Examination By Mr. Clark

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CHAD MODRA

Direct Examination By Mr. O'Connor

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EXHIBITSNUMBERDESCRIPTIONPAGE

2149

Vierling Deposition,
 05/11/2016 - Exhibit 231 -
 12/13/2001 E-mail from Carol
 Vierling to
 kaufmajo@ohsu.edu, Paul
 Stagg, and Connie Murray Re.
 "RF Protocol"

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08:16:12 1 **P R O C E E D I N G S**

2 (Proceedings resumed in open court outside the presence
3 of the jury.)
4

08:29:55 5 THE COURT: Please be seated.

6 Morning, everybody.

7 EVERYBODY: Morning, Your Honor.

8 THE COURT: Counsel, I assume we need to talk this
9 morning about the evidentiary issues that the memos that have
08:30:19 10 been filed on; is that right?

11 MR. COMBS: That's correct, Your Honor.

12 THE COURT: What I think I'd like to do is tell you
13 my thoughts, having read the cases, and let you react to it.

14 So it looks to me, as is not all that uncommon, as
08:30:34 15 though we've got some inconsistent cases in the Ninth Circuit.
16 There is the *Childs* case, which I relied on last time when I
17 admitted the kind of exhibit that's being proposed again.

18 The *Childs* case, by my reading, allows for the
19 admission of the hearsay within hearsay if the document was
08:31:09 20 relied upon by Bard and if Bard had a substantial interest in
21 the accuracy of the document.

22 I do not agree with the defendants that *Childs*
23 required that the hearsay within hearsay satisfy the business
24 records exception. *Childs* didn't address that at all. Now,
08:31:29 25 granted, they were official type documents, car titles and

08:31:32 1 such things. But it didn't analyze anything about the nature
2 of those documents. It focused on the company's reliance and
3 upon -- in a footnote, it mentioned that it had a substantial
4 interest in the accuracy of the document.

08:31:46 5 The *MRT* Construction case, which was decided five
6 years later, followed that same rationale and said that there
7 was a three-step test: One is that the over all document
8 needed to be kept in the regular course of business, the
9 information that otherwise would be hearsay had to be relied
08:32:07 10 upon by that business, and the business had to have a
11 substantial interest in the accuracy of the documents.

12 So *MRT* seemed to adopt *Childs*.

13 There have been cases in the Ninth Circuit that have
14 looked at a different requirement, and that is the requirement
08:32:24 15 that the entity in this case, Bard, verified the accuracy of
16 the information. The primary case that was cited by the
17 defense for that is the *Arteaga*, A-R-T-E-A-G-A, case, but that
18 discussion is dicta. Judge Kozinski's opinion goes on to say
19 that whole discussion is moot because the judge admitted it
08:32:45 20 not for the truth of the matter asserted. So that is all
21 dicta.

22 But there are other cases, like the *Bland* case, that
23 looked at whether or not the entity that kept the record
24 verified the accuracy of the information.

08:32:59 25 Those two lines of cases don't talk about each other.

08:33:03 1 And I -- we didn't find any case that tries to synthesize
2 them.

3 So it appears that they are both lines of authority,
4 and I'm not comfortable looking outside the Ninth Circuit to
08:33:15 5 find the answer. It seems to me I've got to look at
6 Ninth Circuit law.

7 As to whether or not the documents in this case are
8 admissible when those two lines of authority are taken into
9 account I think requires me to do two things: One is look at
08:33:31 10 the documents, I haven't seen yet the documents that are being
11 proposed; and, second, listen to the testimony that the
12 plaintiff proposes to use for foundation, which I understand
13 will be Mr. Modra's testimony, and then decide whether, in
14 light of these two lines of authority, I think it is
08:33:47 15 admissible.

16 Those are my thoughts on those two lines of cases.

17 There is also an argument made by the plaintiff that
18 I can admit these documents and the hearsay within the
19 documents as an adoptive admission. Clearly the rules
08:34:05 20 recognize adoptive admissions. The question is whether Bard
21 took steps that would constitute an adoptive admission. And I
22 don't know the answer to that yet. I don't know what Bard did
23 with the information under the testimony. There are cases
24 suggesting that if an entity acquires information and forwards
08:34:25 25 it as part of its own communication, that is an adoptive

08:34:31 1 admission. And the *Sea-land Service, Inc.* case, the decision
2 by Judge Graber, seems to support that. So that is another
3 possible method for these documents to come in. But, again, I
4 don't know what the testimony will be about how the documents
08:34:47 5 were used.

6 And then, of course, the plaintiff is making an
7 argument that they are admissible for notice to Bard. That's
8 a difficult argument for me to analyze without looking at the
9 documents and asking the question of whether the jury could
08:35:03 10 follow an instruction that they're to consider this
11 information only for notice and not for the truth of the
12 matter asserted. I just don't know the answer to that until I
13 look at the documents.

14 So those are my thoughts having read the cases that
08:35:16 15 you all cited.

16 I'm interested in your thoughts, where you think I've
17 got it wrong, what you think I ought to do in terms of the
18 issue.

19 MR. COMBS: Your Honor, if I may, I've got some
08:35:30 20 samples, and I can show you and kind of walk you through some
21 of these documents and how we intend to use them.

22 I apologize, I don't have them totally matched up,
23 but I think you will -- I think, Your Honor, you will get the
24 gist.

08:35:54 25 Lincoln Combs for the plaintiff, by the way,

08:35:57 1 Your Honor.

2 The documents in question are complaint files. A
3 sales rep gets a call or a doctor reports in an e-mail, or a
4 sales rep or other Bard contact is directly involved and
08:36:16 5 observes a procedure and learns of a complication with their
6 filters. This goes into a complaint file, and it's a pretty
7 thick document.

8 And, Your Honor, if I may approach and give a copy to
9 counsel.

08:36:29 10 THE COURT: You may.

11 MR. COMBS: And this is a compilation. All these
12 documents relate to one report. And there's forms and
13 procedures that Bard follows that go along with this, and I'll
14 show you a couple examples of the forms. But the procedure,
08:36:54 15 Mr. Modra testified extensively in the Booker trial on the
16 foundation. We've listed that in our brief about, you know,
17 all of the steps they take to create these, that they're
18 trained in these, and it's a regular part of their business.

19 So I think all the other parts of the business record
08:37:09 20 exception have been met other than this kind of issue in the
21 *Childs* and the other cases. And I think that's the way
22 Your Honor already ruled in Booker. I think Bard may be
23 moving to reconsider some of that, but they can address that
24 part of it. But I'm focusing on the one issue here of the
08:37:28 25 hearsay within hearsay.

08:37:32 1 If you look on the third page --

2 THE COURT: What's the number of this exhibit?

3 MR. COMBS: I'm sorry, this is Exhibit 3270.

4 THE COURT: All right. This entire thing is 3270?

08:37:48 5 MR. COMBS: Correct, Your Honor. It all relates to
6 one complaint.

7 And the third page of that, which is -- last four
8 digits are 1669 of the Bates number, if you look in the middle
9 of that, there's an event description. And I'm not going to
08:38:04 10 read the whole thing. The details of these are different.

11 Sometimes it's in an e-mail, like I said, or sometimes it's
12 something directly observed by a sales rep that's sitting in
13 on a procedure. Or it could be a phone call or whatever.

14 But here's where the complaint is described. And
08:38:24 15 that text is important because, if you'll turn to it, towards
16 the back of the document, Your Honor, the last four digits are
17 1718.

18 And this is a form that Bard uses to report this
19 information to the FDA. And if you'll look, the text in the
08:38:57 20 middle of this form describing the event matches the event
21 description that I just referenced on these -- third page of
22 the document.

23 So this same text is then not only relied on by Bard,
24 but then delivered to the FDA virtually verbatim.

08:39:25 25 This text in the event description and in the FDA

08:39:30 1 form, MDR form, is what we want to summarize in a 1006 summary
2 of all the complaints.

3 And, Your Honor, I understand there's an argument on
4 substantial similarity. And we can slice that as close as you
08:39:52 5 want, down to fractures that go to the lung. We would argue
6 they're all relevant for a 1006 summary.

7 What our 1006 summary is, Your Honor -- if I may
8 approach, this is -- this is what we're proposing to do, is
9 just basic information on all these complaints with that exact
08:40:31 10 same text that's in the complaint file and then reported to
11 the FDA.

12 THE COURT: Which -- which of the lines corresponds
13 to Exhibit 3270 you just gave me?

14 MR. COMBS: I think it's the top one.

08:40:50 15 THE COURT: No, the language is different --

16 MR. COMBS: Your Honor, it may not -- that one
17 exemplar I gave you may not exactly match.

18 MS. SMITH: It would be page 827.

19 THE COURT: I think it is -- I think it's on
08:41:08 20 page 269.

21 MR. COMBS: They will match. They do match.

22 THE COURT: So turn to page 269. Do you have that?

23 So the first three sentences correspond word for word
24 with what is in Exhibit 3270. Then the rest of the text in
08:41:44 25 269 does not, starting with "The physician is evaluating the

08:41:53 1 course of action."

2 So I'm trying to understand what you've put into the
3 summary from the actual complaint files.

4 MR. COMBS: I think to the extent it doesn't match,
08:42:05 5 Your Honor, we can certainly make it match. I think that came
6 from another section of the -- of the complaint file report --

7 THE COURT: So in what you handed me there's no
8 heading on the columns. What are the columns?

9 MR. COMBS: I'm sorry, Your Honor. Beginning Bates
08:42:26 10 number, complaint number, awareness date, device name, product
11 catalog number, primary FDA code, sex/age, and event
12 description.

13 THE COURT: What is the fourth -- the fifth column?

14 MR. COMBS: Primary FDA code.

08:42:51 15 THE COURT: So 2616, malposition of the device, is an
16 FDA code?

17 MR. COMBS: That's correct.

18 THE COURT: And the next column is age and gender?

19 MR. COMBS: Yes.

08:43:05 20 THE COURT: And is it your intent, in the event
21 description, to quote word for word from what's in the
22 complaint?

23 MR. COMBS: Correct, Your Honor.

24 THE COURT: And in each of these instances will the
08:43:17 25 language you're quoting word for word be found not only in the

08:43:20 1 complaint record detail report, but also in the report to the
2 FDA?

3 MR. COMBS: Correct, Your Honor. To the extent it
4 doesn't, we can certainly correct that.

08:43:31 5 THE COURT: Well, you pointed out in Exhibit 3270
6 that the wording in the report to the FDA is exactly the same
7 as what is the event description in the complaint record.

8 MR. COMBS: Correct, Your Honor. To the extent in
9 our summary it doesn't match that, if there's some additional
08:43:47 10 language like that, record review or whatever, we can fix
11 that, but that is the intent, yes.

12 THE COURT: Is it your understanding that in every
13 one of these complaint files, the language reported to the FDA
14 is taken word for word from the complaint description?

08:44:03 15 MR. COMBS: Yes, Your Honor.

16 THE COURT: Okay.

17 MR. COMBS: And then that leads --

18 THE COURT: Recognize we've got 15 minutes left. So
19 let's really zero --

08:44:14 20 MR. COMBS: I'll be very quick, Your Honor. I won't
21 even point anything else out. That same text goes into the
22 monthly management reports, which you've seen in the listing
23 of complaints at the end. I know that was the issue with the
24 last three pages of the exhibit that you ruled was admissible
08:44:26 25 under *Childs*.

08:44:29 1 So our position is that is extremely reliable because
2 it is not only being reported by medical professionals, not
3 Western Union employees or whatever, people filling out forms
4 in a gun shop like in the cases they cited. These are medical
08:44:41 5 professionals reporting serious medical complications to a
6 medical device company. Bard not only relies on that
7 information, but then turns around and actually reports it to
8 the FDA as if it was reliable.

9 THE COURT: And what exactly are you seeking to move
08:44:55 10 into evidence?

11 MR. COMBS: We want -- the monthly management
12 reports.

13 THE COURT: So neither of these?

14 MR. COMBS: Neither of those. This is like the third
08:45:03 15 part of the triangle of how this information comes in and is
16 used by Bard.

17 THE COURT: Do you have a copy of the monthly
18 management report that corresponds to this?

19 MR. COMBS: And just to be clear, Your Honor, we're
08:45:36 20 seeking to move in that group of monthly management reports
21 and our FRE 1006 summary as well. Correct.

22 THE COURT: But not the underlying complaint?

23 MS. SMITH: Right. Which is the intent of the chart
24 because --

08:45:55 25 MR. COMBS: Do it as a summary, Your Honor.

08:46:04 1 THE COURT: Okay. What is this document number
2 you've handed me?

3 MR. COMBS: That is a monthly management report.

4 THE COURT: What's the exhibit number?

08:46:14 5 MS. SMITH: On the bottom it's Bates stamped.

6 MR. COMBS: I believe it's on the bottom. I don't
7 have --

8 THE COURT: 4504?

9 MR. COMBS: Yeah, that sounds about right,
08:46:21 10 Your Honor.

11 THE COURT: Okay. Is there something in here that
12 corresponds to these documents you've given me?

13 MR. COMBS: I didn't give you the one that exactly
14 corresponds to that complaint file. But you'll see in the
08:46:31 15 last few pages when they have these listing of complaint
16 events, there's an event description that goes along with
17 those and a complaint number, and those exactly match the same
18 text of the report to the FDA and the complaint file event
19 description.

08:46:45 20 THE COURT: And do you have something that
21 corresponds your 1006 chart with monthly management reports?

22 MR. COMBS: It's all the same information.

23 THE COURT: Well, I know that. But do you have
24 something that would allow me to look at your 1006 summary and
08:47:02 25 say these 15 events are reflected in this monthly management

08:47:08 1 report?

2 MR. COMBS: We can definitely do that, Your Honor,
3 yes.

4 THE COURT: But you haven't done that so far?

08:47:13 5 MR. COMBS: I just don't have it all compiled here
6 this morning.

7 MS. SMITH: Based on the complaint ID number, we can
8 certainly take our chart and separate it like that for you.

9 THE COURT: Okay. What is the scope of the kinds of
08:47:25 10 complaints that are in your 1006 summary? Is it just Eclipse?
11 Is it all filters? Is it all products?

12 MR. COMBS: Like I said, we can slice it however we
13 want to. We have one that is 2003 to 2015, all complaints,
14 but --

08:47:40 15 THE COURT: Meaning all products?

16 MR. COMBS: All products. But that can be down to
17 Eclipse or that can be -- it's a spreadsheet, we can sort it
18 however we need to or slice it out --

19 THE COURT: What are you proposing to do?

08:47:51 20 MR. COMBS: We'd like to move for all of it,
21 Your Honor.

22 THE COURT: Why would a complaint about a stent
23 problem be relevant?

24 MR. COMBS: No, Your Honor, these are all filter --
08:47:58 25 filter problems.

08:48:01 1 MS. SMITH: Recovery, G2, and Eclipse.

2 THE COURT: But it's not all products, it's --

3 MR. COMBS: When you said all products, Your Honor,

4 all retrievable IVC filters.

08:48:08 5 THE COURT: So what is in your current 1006 chart?

6 MS. SMITH: Recovery filters, G2 and Eclipse, with

7 the relevant injuries and a cascade from perforation.

8 THE COURT: So all complications for Recovery, G2,

9 G2X, and Eclipse?

08:48:25 10 MS. SMITH: All complications that are relevant to

11 the MDL. So it does not include deployment issues or issues

12 with the catheter. Only injuries that are relevant here.

13 THE COURT: Meaning what?

14 MS. SMITH: Perforations, migrations, fractures, and

08:48:37 15 sometimes with things are left in the body and so they're

16 embedded and aren't able to be removed.

17 THE COURT: Okay. And are you intending to get this

18 in today through a witness?

19 MR. COMBS: We would like to move it into evidence at

08:48:51 20 the beginning of the day, Your Honor.

21 THE COURT: You can't move it in until you've laid

22 the foundation for the business record.

23 MR. COMBS: Our position is Mr. Modra laid that

24 foundation in the last trial.

08:49:02 25 THE COURT: Had to happen in this trial.

08:49:04 1 MR. COMBS: I don't think that is correct,
2 Your Honor, under Rule 104. And I've checked with Weinstein's
3 on that. You can have an evidentiary hearing pretrial to move
4 in evidence that's otherwise not disputed. We've already had
08:49:14 5 that.

6 THE COURT: We've not had any evidentiary hearing
7 that has this 1006 document in question. All we had -- all we
8 had in the last trial was Mr. Modra's testimony in response to
9 the defense questioning about their complaint handling
08:49:28 10 procedures. Now, it was after that that I let in that
11 management report. But there's been no 1004 hearing about
12 this 1006 -- 104 hearing about this 1006 exhibit.

13 MR. COMBS: Fair enough, Your Honor. But as to the
14 monthly management reports, I believe there has been. So we'd
08:49:48 15 like to move those in at the beginning of the testimony today.

16 THE COURT: Well, I'll tell you now I'm not going to
17 admit them without foundation testimony. Now, if what you
18 want to do is ask me through a 104 procedure to rely on what
19 Mr. Modra said, then you've got to give me that testimony.

08:50:05 20 MR. COMBS: We did, Your Honor, in our trial brief.

21 THE COURT: Well, you cited -- you gave me four cites
22 to his testimony. I haven't gone and read that record. I
23 haven't heard anything in response from the defendants about
24 what's --

08:50:14 25 Hold on. Please don't talk while I'm talking.

08:50:17 1 You haven't allowed the defendants to respond to it,
2 so I don't think I have an evidentiary basis for admitting
3 these now.

4 MR. COMBS: Okay. Fair enough, Your Honor.

08:50:26 5 THE COURT: But in light of that, tell me how you
6 want to proceed.

7 MR. COMBS: Then --

8 THE COURT: I'm not saying you can't lay that
9 foundation. I'm just saying it hasn't happened up until now.

08:50:34 10 MR. COMBS: No, I understand, Your Honor. And so
11 we'll do that with Mr. Modra today, yes. That will be our
12 goal.

13 THE COURT: Okay.

14 MR. O'CONNOR: May I consult with him for one second?

08:50:41 15 THE COURT: Well, yeah. We have nine minutes left,
16 so I'm going to hear from defendants.

17 MR. COMBS: Can we, Your Honor, question Mr. Modra
18 outside of the presence of the jury --

19 THE COURT: No. No. I'm not going to take time away
08:50:52 20 from the jury while we do that.

21 MR. COMBS: Well, we've asked to do it so we're not
22 using up time and using the jury's time.

23 THE COURT: There is no time to do that. I mean, the
24 only time would be during the lunch hour, but I think
08:51:03 25 everybody needs the break. I've got a hearing starting at

08:51:06 1 4:30 today. So I think we've got to use trial time to do
2 that.

3 MR. COMBS: Thank you, Your Honor.

4 THE COURT: Okay. We've got eight minutes left,
08:51:13 5 Mr. North, so give me your thoughts on this issue.

6 MR. NORTH: Your Honor, I agree with the Court on the
7 need to hear further testimony as to resolve the hearsay
8 issue, so I'm not going to address that right now.

9 But I would like to point out that hearsay is only
08:51:28 10 the first problem here. There are very serious 402 and 403
11 issues with what they are seeking to do. They are seeking to
12 put in front of this jury hundreds of reports of other
13 incidents. Often unverified.

14 And what is perhaps most unfair, in the defense's
08:51:47 15 view, about this evidence under 403 is the fact that so much
16 of this evidence has been created by the plaintiff's attorneys
17 themselves by filing lawsuits.

18 We file a complaint form with the FDA, and we
19 investigate, we create one of these complaint files for every
08:52:05 20 lawsuit that's filed here in this Court. So 3,000-plus of
21 these events and complaint files have to do with these
22 lawsuits.

23 But put that aside, there's plenty of Ninth Circuit
24 precedent which we have cited about limitations on putting
08:52:24 25 other incident evidence in, the need for substantial

08:52:26 1 similarity, the need to limit that evidence to a discrete
2 number of cases or events, if you're going to let it in,
3 because of the prejudicial effect of it.

4 And then, as an aside, I would note with these
08:52:39 5 management reports, there's a plethora of other relevance
6 issues because each of these reports have volumes of
7 information about competitor intelligence involving other
8 products, profits, recalls on stents. I mean, they're just
9 full of information unrelated to filters that never should be
08:52:58 10 part of this record.

11 THE COURT: In which documents?

12 MR. NORTH: The management reports. They are
13 proposing to introduce 20 management reports that just have
14 tons of information about the business of Bard Peripheral
08:53:11 15 Vascular totally unrelated to filters.

16 But even if you focus only on these other incidents,
17 we believe under the Ninth Circuit precedent not only are
18 there hearsay issues that still need to be resolved, but there
19 are relevance and 403 issues. If they're able to put in front
08:53:30 20 of this jury this 1006 chart of thousands, or at least
21 hundreds, of other events involving all of our filters over a
22 ten-plus-year period without showing substantial similarity to
23 each event, as they're required to do, without -- at many
24 points of instances, the information having never been
08:53:56 25 verified by Bard, merely anecdotal reports or reports

08:54:00 1 contained in plaintiff's profile forms filed in this
2 litigation, I don't see how we can get a fair trial.

3 And I think this is a perfect situation for the
4 application of Rule 403.

08:54:13 5 THE COURT: Well, where in your brief, Mr. North, did
6 you cite the substantial similarity to case law?

7 Are you talking about the cases you're citing at the
8 bottom of page 3 and the top of page 4?

9 MR. NORTH: Yes, Your Honor.

08:54:53 10 THE COURT: You're not talking about substantial
11 similarity in your discussion, you're talking about cumulative
12 and prejudicial.

13 MR. NORTH: I'm sorry, Your Honor. In some of the
14 parentheticals. For example, in *Arnold versus Sam's Club*. I
08:55:09 15 think in our haste to get that filed we didn't specify it. We
16 did cite the concepts in there.

17 THE COURT: Well, I have not focused on that issue
18 because it wasn't argued. So I haven't read these cases with
19 that substantial similarity question in mind.

08:55:24 20 Let me make sure I understand your argument.

21 Let's assume we could narrow their 1006 exhibit to
22 nothing but filter complications for the G2 line of the kind
23 that are at issue in this case, migration, tilt, fracture, and
24 perforation. And let's say hypothetically there's 200 of
08:55:45 25 those. What is your argument as to why that's not relevant?

08:55:51 1 MR. NORTH: Number one, Your Honor, I think that they
2 have a problem in showing substantial similarity. First of
3 all, we heard yesterday from Dr. McMeeking he doesn't even
4 think perforation is an issue. Tilt in this case, the
08:56:03 5 evidence is going to be is four degrees.

6 THE COURT: I'm sorry to cut you short. We've only
7 got three minutes left now.

8 So one of your arguments is it's irrelevant because
9 these incidents are not substantially similar.

08:56:14 10 MR. NORTH: Right.

11 THE COURT: And you're relying upon the *Arnold* case
12 for that proposition? And similar authority --

13 MR. NORTH: And *Daniels* too.

14 THE COURT: Okay. So one argument is that even
08:56:29 15 though they're the same line of filter and the same kinds of
16 complications, they have to clear some additional substantial
17 similarity burden?

18 MR. NORTH: Right.

19 THE COURT: Okay. That is one argument.

08:56:39 20 What else do you have in the way of arguments that
21 those categories are not relevant?

22 MR. NORTH: No, I think that's the ground for the
23 relevance objection. Then you move to the 403.

24 THE COURT: Okay. So let's assume for a minute we
08:56:52 25 narrow the 1006 to G2 line of filters and those four

08:56:57 1 complications. I'll look at the substantial similarity
2 argument.

3 What is the 403 argument?

4 MR. NORTH: Your Honor, there are many -- I believe
08:57:05 5 there are a number of Ninth Circuit cases, and those are not
6 cited in the brief, but that talk about the nature of
7 extensive evidence of other incidents being highly prejudicial
8 and imposing limitations on the examples that can be
9 presented.

08:57:21 10 I think we have to remember, too, that we're not
11 arguing that the number of complaints can't be put in front of
12 this jury. We're talking about all this uncorroborated
13 detail.

14 THE COURT: Okay. So you say there are 403 cases
08:57:33 15 that you haven't cited?

16 MR. NORTH: I believe so. I will go check.

17 THE COURT: I obviously can't look at those cases if
18 you've not cited them.

19 MR. NORTH: Right.

08:57:41 20 THE COURT: So that's your relevancy and your 403
21 argument. If we narrow 1006 to filters and these
22 complications.

23 MR. NORTH: Yes.

24 THE COURT: And you've got your hearsay argument.

08:57:56 25 MR. NORTH: Right.

08:57:57 1 THE COURT: But do you agree with my description of
2 the Ninth Circuit law as it stands with the *Childs* line of
3 cases and the verification line of cases?

4 MR. NORTH: I think we read the *Childs* case
08:58:07 5 differently than the Court. We read it as an actual business
6 record of one company being incorporated into the business
7 records of another.

8 THE COURT: All right. And I've read that argument
9 and I don't agree with it. I don't think *Childs* or the other
08:58:20 10 case, *MRT*, says that.

11 Besides those hearsay arguments and your relevancy,
12 substantial similarity, and the 403 cases you're going to give
13 me, do you have any other argument against their 1006
14 document?

08:58:42 15 MR. NORTH: No, Your Honor, I don't believe so.

16 THE COURT: Okay. We're down to one minute
17 beforehand. Let me tell you what I'd like to do.

18 It seems to me that whatever is in the 1006, it
19 should at least be limited to the G2 line of filters and the
08:58:56 20 four categories of complications we've talked about.

21 And maybe that's what it already is limited to. But
22 if not, it seems to me anything else should be taken out
23 because it's plainly not relevant to this case.

24 We will look at the substantial similarity cases over
08:59:12 25 the lunch hour. If you can get somebody to give us the 403

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08:59:16 1 case cites, I'll look at that as well.

2 I'll be happy to look at whatever cases plaintiff
3 wants to identify in response to the substantial similarity
4 cases.

08:59:25 5 And I think what we need to do is have the plaintiff
6 lay whatever foundation you think you can through Mr. Modra,
7 and then we'll have to revisit this issue after I've looked at
8 the case law and I can hear both sides' arguments.

9 MR. NORTH: Thank you.

08:59:40 10 THE COURT: Okay. So let's proceed in that manner.
11 So go ahead and lay the foundation with Mr. Modra.

12 All right. We're at 9 o'clock. We'll bring the jury
13 in.

14 (The jury entered the courtroom at 9:00.)

09:01:02 15 THE COURT: Good morning, ladies and gentlemen.
16 Thanks for being with us this morning. We're doing a little
17 organizing and solving computer problems, but we're going to
18 get started.

19 So we are continuing with the plaintiff's evidence.

09:01:14 20 MR. CLARK: We are, Your Honor. The plaintiff would
21 call Dr. David Garcia.

22 THE COURTROOM DEPUTY: Dr. Garcia, if you'll stand
23 right here, raise your right hand, please, sir.

24

25

DIRECT EXAMINATION - DAVID GARCIA, M.D.

1 **DAVID GARCIA, M.D.,**
2 called as a witness herein, after having been sworn or
3 affirmed, was examined and testified as follows:

4 MR. CLARK: May I introduce myself to the jury?

09:01:46 5 THE COURT: Yes, you may.

6 MR. CLARK: Ladies and gentlemen, my name is
7 Shannon Clark. I'm on the team of attorneys who represents
8 Doris Jones.

9 D I R E C T E X A M I N A T I O N

09:01:54 10 BY MR. CLARK:

11 Q Dr. Garcia, could you introduce yourself to the jury.

12 A Good morning. My name is David Garcia.

13 Q Tell the jury what you do for a living.

14 A I'm a hematologist. I practice at the University of
09:02:02 15 Washington Seattle.

16 Q What is hematology? What type of medicine do you
17 practice?

18 A I specialize in disorders of the blood, and in particular
19 my research and clinical practice focus is in blood clotting
09:02:16 20 and its treatment and prevention.

21 Q And are you board certified in hematology?

22 A I am.

23 Q You mentioned you work at the University of Seattle. Is
24 that a hospital setting?

09:02:27 25 A Yes. University of Washington is a large tertiary care

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09:02:30 1 medical center. I also do some time at the Veterans
2 Administration Hospital in Seattle and the Seattle Cancer Care
3 Alliance.

4 Q Are you fully accredited at those institutions?

09:02:42 5 A At all of them, yes.

6 Q Do you also teach?

7 A I do. I teach medical students. I teach trainees who
8 have just left medical school, they're called residents, or
9 fellows, interns, and across that spectrum.

09:02:57 10 Q And the jury may be familiar. There are a number of
11 different types of professors: Associate professors, adjunct
12 professors, full professors. What type of professor are you?

13 A So my title is full professor in the department of
14 internal medicine, division of hematology.

09:03:16 15 Q Looking at the type work that you do, the jury has already
16 heard a lot of information about blood clots, DVT, pulmonary
17 embolism. Can you briefly explain why patients develop blood
18 clots?

19 A Well, it can be the subject of a long lecture, but I'll
09:03:32 20 try to be very brief.

21 Blood clots form in patients' vessels for many
22 reasons, but fundamentally what happens when a patient forms a
23 blood clot is a very complex system in the body, which is
24 designed evolutionarily to help us not bleed to death, goes
09:03:55 25 awry. And rather than a clot forming in response, let's say

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09:03:58 1 to an injury, like cutting yourself shaving, a clot forms
2 spontaneously within a vessel where, ideally, blood should be
3 flowing freely.

4 Q And what's the difference between DVT and pulmonary
09:04:14 5 embolism?

6 A DVT means a blood clot is forming in one of the large
7 blood vessels or deep veins, typically of the legs. And
8 pulmonary embolism refers to a blood clot that is lodged in
9 one of the blood vessels in the lungs, that carries blood
09:04:33 10 through the lungs.

11 Q Now, in your clinical practice, can you explain to the
12 jury what it is that you do, sort of day in day out, in terms
13 of managing the care of patients who are either at risk of
14 developing DVT or PE or have DVT or PE?

09:04:49 15 A So I take care of a lot of patients who ask my advice
16 about, for example, the risks and benefits of taking blood
17 thinning medications to either prevent a second or third blood
18 clot from occurring or, in some cases, to prevent a first
19 blood clot from occurring if they're a patient who is at risk
09:05:10 20 but hasn't yet experienced such an event.

21 MR. CLARK: Gay, would you pull up Exhibit 2467.

22 BY MR. CLARK:

23 Q Doctor, we're going to show you Exhibit 2467. Can you
24 identify what this document is.

09:05:26 25 A This is an expert report that I prepared along with

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09:05:29 1 Dr. Michael Streiff as part of my involvement with this
2 litigation.

3 Q Who is Dr. Michael Streiff?

4 A He's a hematologist at Johns Hopkins Hospital who also
09:05:40 5 specializes in blood clots.

6 MR. CLARK: And, Gay, can you please turn to page 12
7 of the report.

8 BY MR. CLARK:

9 Q Doctor, can you identify what is -- it's a little
09:05:48 10 confusing because the bottom of the page says 2, but in the
11 lower right-hand corner we see .012. What is beginning on
12 .012?

13 A This is my curriculum vitae or CV.

14 Q How long is the CV?

09:06:06 15 A I don't remember. I think it is more than 20 pages long.

16 Q Would 27 pages sound right?

17 A That could be right.

18 Q And what does a CV do?

19 A CV just provides -- it's like a resume. It provides an
09:06:20 20 overview of jobs that I've held, titles and promotions that
21 I've had, and it also provides a list of various works that
22 I've published over the years, be they book chapters,
23 peer-reviewed papers and articles, national and international
24 meetings at which I've been invited to give presentations.

09:06:39 25 Q About how many times have you been a published author?

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09:06:44 1 A I think if you just count peer-reviewed papers, it is
2 approaching about 100 peer-reviewed articles that I have been
3 a co-author or author of.

4 Q And do those generally relate to the treatment of blood
09:06:57 5 clotting disorders?

6 A Almost all of them.

7 Q And have you published any information concerning the use
8 of IVC filters?

9 A Yes. There's at least one article in which I -- that was
09:07:11 10 the principal subject of the article that was published, I
11 think four, five years ago now, with some co-authors. And
12 then IVC filters are likely mentioned in several of the other
13 papers, even though that's not their principal focus.

14 Q Understood.

09:07:27 15 Is it fair to say that you believe, Doctor, that you
16 have a thorough understanding of the use of IVC filters as it
17 relates to the treatment or for DVT/PE?

18 A Yes, I think it's my job to have such an understanding.

19 Q And I forgot to ask you, where did you go to medical
09:07:42 20 school?

21 A I attended medical school at the University of Alabama in
22 Birmingham, and then I did my residency in internal medicine
23 at Johns Hopkins Hospital, and completed my fellowship
24 training in hematology at the University of Washington in
09:07:54 25 Seattle.

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Q And in terms of your post training career, is it fair to say that you have dedicated a majority of your professional practice to the study and application for treating DVT and PE?

A Yes. The treatment of DVT and PE has been the focus of both my clinical practice and my research for essentially my entire career.

Q Doctor, can you tell the jury what you were asked to do in this case.

A Yes. So I was asked to provide an evidence-based opinion about the -- what is known about the risks and benefits of inferior vena caval filters for the treatment of patients with DVT/PE, as well as the prevention of DVT in patients who may be at risk for such.

I was also asked to look at the medical records of Mrs. Doris Jones and determine -- and form an opinion about whether she had suffered an injury as a result of her filter placement and whether she was at risk for complications from that injury.

Q And did you, in fact, formulate opinions concerning those two subjects?

A I did.

Q And are your opinions based upon your training, experience, and education in the area of hematology?

A Yes.

Q And are the opinions that you're going to be expressing

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09:09:14 1 here today formulated to a reasonable degree of medical
2 probability?

3 A They are.

4 Q Are you being paid for your work in this case?

09:09:21 5 A Yes, I am.

6 Q How much per hour?

7 A I charge \$700 per hour for any work related to this or any
8 other legal matter.

9 Q What about if you have to come to testify for a day,
09:09:31 10 what's -- do you have a daily rate?

11 A Yes. I charge \$5,000 per day to appear in court.

12 Q Doctor, is that the same rate you charge for work whether
13 you're working for a plaintiff or a defendant?

14 A Yes. For the last several years I've charged that rate
09:09:47 15 for any medical malpractice work in which I'm a consultant.

16 Q Any other type of legal work, same --

17 A Any legal work, yes.

18 Q And are we also paying your travel expenses to come here
19 and talk to the jury?

09:10:00 20 A Yes.

21 Q Now, let's talk about your opinions in the case. Let's
22 focus first on the -- addressing patients who have clots. And
23 let me make that distinction.

24 You mentioned two things. You talked about treating
09:10:14 25 patients with clots and also preventing clots. So can you

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09:10:18 1 explain to the jury what the difference between those are. I
2 think it is self-evident, but to be sure.

3 A Sure. So, in the first case, we're talking about a
4 patient who has been diagnosed with a DVT or PE. And then
09:10:30 5 we're trying to advise that patient about what intervention or
6 interventions can minimize the likelihood that they have
7 problems related to that DVT or PE.

8 When we talk about prevention or primary prevention,
9 a patient has not yet experienced a blood clot, but may be at
09:10:54 10 such a high risk for a blood clot that the doctors are
11 contemplating some sort of pharmacologic or other intervention
12 in sort of preemptive fashion to prevent the clot from ever
13 happening.

14 Q In terms of treatment, to your knowledge, is there any
09:11:11 15 generally accepted indication for IVC filter placement for the
16 treatment of blood clots?

17 A I would say the widely acknowledged rare situation in
18 which filters are considered or possibly indicated is patients
19 who have experienced a fairly recent DVT or PE and have an
09:11:38 20 absolute contraindication to anticoagulant or blood thinning
21 therapy.

22 Q What do you mean by a contraindication to anticoagulant
23 therapy?

24 A Well, some examples of that would be a patient is actively
09:11:53 25 bleeding. We can't give such a patient an anticoagulant

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09:11:57 1 because it could make the bleeding that's already happening
2 much worse or catastrophic. Or a patient whose had very
3 recent surgery and so they have blood vessels that have been
4 traumatized as part of the surgery and are at risk to begin
09:12:11 5 bleeding cannot receive anticoagulants in many situations. So
6 these would be absolute -- situations where anticoagulants are
7 absolutely contraindicated.

8 Q Now, would you treat all such patients with IVC filters at
9 any given time?

09:12:30 10 A I would strongly consider placing an IVC filter in a
11 patient with recent objectively confirmed DVT or PE if he or
12 she had an absolute contraindication to anticoagulant therapy.
13 But if -- but -- once the patient is, let's say, more than
14 roughly a month separated from their DVT or PE, if they then
09:12:59 15 developed a contraindication to anticoagulant therapy, I
16 probably would not suggest an IVC filter in that situation.

17 Q Why would your opinion about the use of an IVC filter
18 change in that context?

19 A Well, because, as we're going to, I think, talk about, I'm
09:13:16 20 not convinced that the benefit of IVC filters has been well
21 established, and that once we're beyond one month from the
22 diagnosis of a blood clot, the daily risk of withholding
23 anticoagulation is substantially smaller and gets lower as
24 time goes on. And so I would not recommend a treatment like
09:13:47 25 filters where there are known complications, no high quality

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09:13:53 1 evidence of benefit in a patient where I felt the risk of
2 simply withholding anticoagulant therapy temporarily was
3 fairly low.

4 Q Okay. Let's talk about the information that's out there
09:14:06 5 about IVC filter use in terms of treating blood clots. Can
6 you explain to the jury what types of data or studies are out
7 there.

8 A Sure. So when we make medical decisions about how to
9 treat patients or diagnose problems, we tend to look at
09:14:26 10 clinical research, and there are many types of clinical
11 research studies. The most basic or lowest quality of
12 clinical research would be anecdote, or what we call sometimes
13 case reports. So this would be, for example, a doctor
14 publishing a paper saying I treated a couple of patients with
09:14:46 15 this condition in this fashion and they seemed to do okay.

16 The next level of quality, moving from down to up,
17 would be larger observational studies. So these are sometimes
18 called registries, cohorts. They can be prospective, meaning
19 you start the study and then watch how patients do going
09:15:12 20 forward, or retrospective, meaning we can look at data that
21 already exists, let's say in an electronic health system, or
22 paper medical records, and try to figure out what happened in
23 the past.

24 But the important part is they're observational
09:15:28 25 studies, meaning there was no attempt to control how patients

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09:15:35 1 were treated, which patients got which therapy. We're just
2 observing what happened in so-called real world practice and
3 describing the outcomes.

4 The best type of study is a study where we say we've
09:15:49 5 got a treatment, an intervention, we'll call it, and we want
6 to compare it to some other approach of management, and we'll
7 call that a control.

8 And we randomly assign patients to either receive the
9 intervention or experimental therapy, or the traditional or
09:16:11 10 control therapy. And we observe whether the outcome that
11 we're trying to prevent or avoid happens more frequently in
12 one group than the other.

13 Ideally, such a study would be double-blinded,
14 meaning neither the patient nor the doctor knows which
09:16:30 15 treatment they got, because that gives it the highest level of
16 scientific rigor.

17 Q Is that because there is an avoidance of bias in the
18 double-blind?

19 A Right. So there are all kinds of biases that can be
09:16:43 20 introduced in clinical research. And as you move up that
21 hierarchy you just described, I just described, the potential
22 for bias decreases, where at the very top in a double-blind
23 randomized control trial it is the least possible potential
24 for bias.

09:17:01 25 Q And with respect to IVC filter use, do we have any

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09:17:04 1 double-blind studies like that?

2 A No.

3 Q Do we have other studies that would be in that top tier
4 category?

09:17:12 5 A There are two studies that I'm aware of in which patients
6 were randomly assigned to either receive an IVC filter or not.

7 Q What are those studies called?

8 A PREPIC and PREPIC2.

9 MR. CLARK: Gay, could you please bring up 7230.

09:17:34 10 BY MR. CLARK:

11 Q Can you identify the document that's listed as
12 Exhibit 7230, sir?

13 A Yes. This is a publication describing the long-term
14 follow-up results of the PREPIC study.

09:17:49 15 Q And what is the publication that this appears in?

16 A It was published in the journal Circulation.

17 Q Is that considered -- is this article considered reliable
18 and authoritative in the field?

19 A Yes.

09:18:05 20 Q Doctor, could you explain what the PREPIC study was
21 designed to do?

22 A Yes.

23 So the PREPIC study enrolled about 400 patients, all
24 of them had either pulmonary embolism or were -- or deep vein
09:18:25 25 thrombosis that was felt to put them at high risk for

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09:18:27 1 pulmonary embolism, and randomly assigned these patients to
2 either have a filter placed, a permanent filter placed, or
3 not.

4 All the patients in the study received
09:18:43 5 anticoagulation therapy. So both groups of the study received
6 anticoagulation therapy for a minimum of three months, after
7 which the decision to continue anticoagulation therapy was
8 left up to the local doctor and the patient.

9 Q And what were the results of the study?

09:19:06 10 A So the primary outcome of the study was at 12 days all
11 patients in the trial underwent a scan of their lungs to
12 determine whether they had developed a new pulmonary embolism
13 that wasn't there when the study started. And there was a
14 statistically significant decrease in the rate of detectable
09:19:29 15 pulmonary embolism among the patients who got the filters.
16 However, there was no difference in mortality. That is,
17 overall rate of death.

18 Q Was there a difference in the rate of the risk of leg DVT
19 long-term in the study?

09:19:49 20 A Yes. So one of the key other outcomes from this study was
21 follow-up that was done two years after filter placement and
22 eight years after filter placement. And at both time points,
23 the authors found a statistically significant increase in the
24 risk of deep vein thrombosis either involving the legs or the
09:20:14 25 inferior vena cava itself among the patients who had gotten

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09:20:17 1 filters.

2 Q And, Doctor, you mentioned that this study was looking at
3 the development of new PEs; correct?

4 A Right.

09:20:24 5 Q And sometimes the literature refers to recurrent PE. Are
6 those the same things?

7 A Yes. In this context, that's what I'm talking about.

8 Q Doctor, in your opinion, does this PREPIC1 study establish
9 that retrievable filters reduce the risk of death from PE?

09:20:41 10 A No.

11 Q Why not?

12 A Well, the rate of fatal pulmonary embolism was not found
13 to be different in the two groups at any of the time points.

14 But, furthermore, the study doesn't involve retrievable
09:20:57 15 filters. It involves permanent filters. So I don't think we
16 can extrapolate any of its findings to retrievable filters,
17 which is what you asked me about.

18 But there are a couple of other design issues with
19 the study that potentially limit the validity of its findings.

09:21:14 20 One is, what I mentioned a moment ago, the uncontrolled nature
21 of anticoagulation. Meaning after the first three months, the
22 study protocol did not dictate whether patients could or
23 should receive anticoagulation therapy. And the challenge is
24 when you leave a decision like that up to the local treating
09:21:37 25 doctor, you lose control over the potential for bias and the

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09:21:42 1 way in which anticoagulation is used or not used. And that
2 could -- since anticoagulation could affect the key outcomes
3 of the trial, namely recurrent pulmonary embolism, it could
4 potentially create confusion in what you're observing and the
09:22:01 5 results between filter and no filter placement. The variable
6 of interest.

7 The other challenge with this study -- well, I
8 already mentioned the fact that the filters were permanent and
9 not retrievable.

09:22:20 10 Q So would this study support the proposition that
11 retrievable filters reduce the occurrence of PE in general,
12 separate and apart from death?

13 A No. For the reasons I mentioned, I don't think it is -- I
14 don't think it clearly establishes that with certainty. I
09:22:37 15 didn't mention that there's another challenge with respect to
16 the long-term follow-up results, and that's the lack of
17 blinding.

18 The fact that the physicians and patients in the
19 trial knew whether a filter had been put in or not may have
09:22:53 20 changed their likelihood of ordering diagnostic tests, looking
21 for pulmonary embolism, which was the key outcome. And that's
22 something we call ascertainment bias. And so once you
23 introduce ascertainment bias, you -- like that, you reduce the
24 certainty or the validity of the ultimate findings and rates
09:23:17 25 of pulmonary embolism.

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Q You mentioned that there's another study, PREPIC2. Let's look at that for a second.

MR. CLARK: Gay, could you please pull up Exhibit 7230.

I apologize. I meant 4147. Could you please pull that up.

BY MR. CLARK:

Q Doctor, could you identify this document for us.

A Yes. This is a manuscript describing the results of the PREPIC2 trial.

Q Is this -- what publication does this manuscript appear in?

A The Journal of the American Medical Association.

Q Is that a reliable publication?

A Yes.

Q Is this article considered authoritative and reliable in the field?

A Yes.

Q Let me direct your attention, Doctor, to page 6, table 3.

And before we go there, could you explain to the jury what PREPIC2 was designed to do.

A So PREPIC2 is very similar to PREPIC1, with a couple of key differences. First of all, all the patients here had experienced pulmonary embolism and, in fact, they were selected based on clinical characteristics that the doctors

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09:24:45 1 thought made their -- made them at particularly high risk of
2 death from their pulmonary embolism.

3 And the hypothesis they were trying to test in this
4 trial was can we reduce the risk of death in this very high
09:25:02 5 risk population of patients by, in addition to anticoagulating
6 them, inserting an IVC filter. And in this case, it was a
7 retrievable IVC filter that was studied.

8 Like PREPIC1, there were about 200 patients in each
9 arm. All patients received anticoagulation but, in this case,
09:25:22 10 they received it for the duration of the study, which is six
11 months. And half the patients were randomly assigned to get
12 filters, the other half received only the anticoagulant
13 therapy. And the principal outcome that they were going to
14 look at, principal three outcomes, were death, fatal pulmonary
09:25:44 15 embolism, and nonfatal pulmonary embolism in the two groups at
16 the end of three months.

17 Q And what did they find when they looked at that?

18 A So there was no difference in any of those outcomes
19 between the two groups. At least not a statistically
09:26:03 20 significant difference in any of those outcomes.

21 Q Did any of the patients in the filter group have a
22 recurrent or new pulmonary embolism?

23 A Yes. At three months follow-up, six of the 200 patients
24 who received an IVC filter had experienced recurrent pulmonary
09:26:20 25 embolus.

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09:26:24 1 Q And how many, if any, of those patients died from the
2 pulmonary embolus?

3 A According to the document, all six patients -- all six of
4 those patients died from fatal PE.

09:26:35 5 Q Did any of the patients in the group that received only
6 anticoagulation therapy die?

7 I'm sorry, did any of them develop PE?

8 A Yes. Three such patients in the anticoagulation group
9 alone experienced recurrent pulmonary embolism.

09:26:51 10 Q Did any of those patients die?

11 A Two of them.

12 Q What conclusions, Doctor, do you draw from this study?

13 A Well, the first conclusion I draw is that even in this
14 high risk population of patients, anticoagulation therapy

09:27:07 15 alone was highly effective. The rate of death from pulmonary
16 embolism was 1 percent in the group that did not receive
17 filters.

18 The second conclusion I draw is that filters are not
19 universally effective at avoiding either pulmonary embolism or
09:27:27 20 death. And, in fact, although these differences are not
21 statistically significant, I would say the observation that
22 more patients died of PE in the filter group than in the
23 control group raises questions about whether filters even do
24 what they're intended to do, which is avoid fatal pulmonary
09:27:47 25 embolism.

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09:27:50 1 Q Between PREPIC and PREPIC1, in your opinion, does one
2 study have more power or validity compared to the other?

3 A Well, I think -- while we're talking about retrievable
4 filters, the PREPIC2 is a more applicable study because it did
09:28:07 5 use a retrievable filter. I think it's also a study I would
6 rely on more because the duration of anticoagulant therapy was
7 more carefully controlled and uniform between the two study
8 groups. And it's also a much more modern study. And so if
9 I'm making decisions today about patient care or conclusions
09:28:30 10 today about relative safety and benefits and efficacy, I'd
11 rather use the more modern data.

12 Q Based on this analysis, Doctor, did you formulate an
13 opinion as to the available data that's out there, what it
14 suggests concerning the use of retrievable IVC filters as a
09:28:50 15 means of treating DVT or PE?

16 A Concerning all available data about retrievable IVC
17 filters, I don't think there's any high quality evidence that
18 they have a beneficial effect or a net benefit for patients
19 with DVT or PE.

09:29:14 20 Q Are you aware of any peer-reviewed high quality evidence
21 that would support the statement that filters save lives?

22 A No.

23 MR. CLARK: Your Honor, at this point I would move to
24 admit, subject to 803(18), Exhibit 4147.

09:29:29 25 THE COURT: Well, the document doesn't come in under

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09:29:31 1 803(18); right?

2 MR. CLARK: I just want to have him read something to
3 the jury from it.

4 THE COURT: Okay. I think you need to identify where
09:29:39 5 you want to have it read, and then I'll hear if there's an
6 objection.

7 BY MR. CLARK:

8 Q Doctor, could I ask you to look at page 1 of Exhibit 4147.

9 And can I direct your attention to the Conclusions
09:29:58 10 and Relevance section of this article.

11 A I'm looking at it.

12 MR. CLARK: Your Honor, would Dr. Garcia be permitted
13 to read the Conclusions and Relevance paragraph?

14 THE COURT: Any objection?

09:30:12 15 MR. NORTH: No objection, Your Honor.

16 THE COURT: All right. You may.

17 THE WITNESS: "Among hospitalized patients with
18 severe acute pulmonary embolism, the use of a retrievable
19 inferior vena cava filter plus anticoagulation compared with
09:30:25 20 anticoagulation alone did not reduce the risk of symptomatic
21 recurrent pulmonary embolism at three months. These findings
22 do not support the use of this type of filter in patients who
23 can be treated with anticoagulation."

24 BY MR. CLARK:

09:30:42 25 Q Do you agree with that conclusion?

DIRECT EXAMINATION - DAVID GARCIA, M.D.

09:30:44 1 A Yes.

2 Q Doctor, let's shift gears quickly here and go to the use
3 of IVC filters for prevention of PE and DVT. Are there any
4 high powered quality studies out there that would give support
09:30:55 5 to the idea that it is a good idea to use IVC filters to
6 prevent DVT or PE?

7 A No, I'm not aware of any high quality data to suggest that
8 filters should be deployed in a preemptive fashion.

9 Q Based on the absence of that data, do you have an opinion
09:31:11 10 as to whether filters could be claimed to be effective in
11 preventing PE or DVT in patients at risk for those?

12 A I think that is an unproven hypothesis.

13 Q Would the statement that filters save lives, in your
14 opinion, be an unproven hypothesis?

09:31:36 15 A Yes.

16 Q Now, let's talk about Mrs. Jones. You have some opinions
17 concerning your review of her records; correct?

18 A Yes.

19 Q And what is your understanding of the status of where the
09:31:49 20 filter fragment is in her body?

21 A My understanding is that she has a fragment of her filter
22 lodged in the artery that supplies the right middle lobe of
23 the lung with the oxygenated blood.

24 Q How would the filter fragment have gotten there?

09:32:06 25 A So when blood flows from the inferior vena cava, which is

DIRECT EXAMINATION - DAVID GARCIA, M.D.

09:32:12 1 where the filter originally resided, it flows into the right
2 atrium, then the right ventricle, which are two chambers of
3 the heart, and then out into the pulmonary arteries, which are
4 the vessels that take deoxygenated blood to the lungs for it
09:32:32 5 to be reoxygenated. And the filter would have passed along
6 that course.

7 Q Based upon your understanding of hematology, do you
8 believe that Mrs. Jones is in any danger from the filter
9 fragment that is in her pulmonary artery?

09:32:48 10 A Yes.

11 Q What are the dangers?

12 A Well, we never want to have a foreign object in the
13 flowing blood because foreign objects, through a variety of
14 mechanisms, can cause clots to form where we don't want them
09:33:04 15 to.

16 Q What are some of those mechanisms?

17 A For one thing, in a case like this, the presence of this
18 filter fragment is creating local turbulence, and turbulent
19 blood flow is a well-known cause of, or potential cause of
09:33:28 20 blood clotting.

21 Another issue is that when we expose a foreign
22 material, whether it's a catheter, a stent, a filter fragment,
23 to the flowing blood, it can trigger a biochemical reaction
24 that just occurs naturally in the body that promotes the
09:33:49 25 formation of clots.

DIRECT EXAMINATION - DAVID GARCIA, M.D.

09:33:51 1 Q So is that the risk that she is exposed to with the
2 fragment of the filter in her pulmonary artery?

3 A That is the principal risk that I'm concerned about is
4 that this fragment sitting in her pulmonary artery could
09:34:05 5 induce the formation of a blood clot.

6 Q And if it were to induce the formation of a blood clot,
7 what could happen?

8 A Well, one possibility is that the artery where the
9 fragment is sitting could become occluded, thereby preventing
09:34:21 10 that portion of her lung from reoxygenating her blood, which
11 could lead to low oxygen levels and be dangerous.

12 Another possibility is that the -- if a clot begins
13 to form, clot can beget clot, and it could enlarge in either
14 direction. But if it enlarges proximally, that is toward the
09:34:46 15 heart, toward the larger caliber blood vessels, it could
16 actually put stress on the heart, leading to either low blood
17 pressure or potentially even an arrhythmia, like the heart
18 suddenly stopping.

19 MR. NORTH: I'm sorry to interrupt.

09:35:01 20 I'm going to object. This is outside of the scope of
21 his report.

22 THE COURT: Is this in the report, Mr. Clark?

23 MR. CLARK: Well, we talked about the risk, and it is
24 just a follow-up concerning what could happen if the risk --

09:35:12 25 THE COURT: Is that the statement in the report?

DIRECT EXAMINATION - DAVID GARCIA, M.D.

09:35:13 1 MR. CLARK: I don't believe so. We'll move on,
2 Your Honor.

3 THE COURT: The objection is sustained.

4 BY MR. CLARK:

09:35:19 5 Q Dr. Garcia, it's my understanding that Bard is going to
6 bring a witness into this case to tell the jury that because
7 of the location of this filter being in a high-flow area, that
8 Mrs. Jones is really not at risk for developing a clot.

9 Do you agree with that?

09:35:37 10 A No.

11 Q Why not?

12 A Well, we see blood clots form in so-called high flow
13 vessels all the time. Indeed, 5 percent of patients with IVC
14 filters can develop local blood clots in the filter, on the
09:35:53 15 filter itself, and the inferior vena cava is certainly at
16 least as high flow of an area as the pulmonary artery.

17 Another example of a high flow state where we see
18 blood clots is patients with coronary artery stents. There's
19 high flow through the artery, but those stents, if not
09:36:14 20 properly treated, often form clots --

21 MR. NORTH: I'm sorry to interrupt.

22 I'm going to object again. Outside of the scope of
23 his report.

24 THE COURT: Mr. Clark?

09:36:23 25 MR. CLARK: One second, Your Honor.

DIRECT EXAMINATION - DAVID GARCIA, M.D.

09:36:34 1 Your Honor's, this was in response to Dr. Hurst's
2 rebuttal response opinions. I think that's fair game since
3 that has been injected by Bard.

4 THE COURT: Was that in the rebuttal, a rebuttal
09:36:44 5 report from this expert?

6 MR. CLARK: There was no rebuttal report, Your Honor.

7 THE COURT: Objection is sustained.

8 BY MR. CLARK:

9 Q Doctor, with respect to -- do you have any other opinions
09:36:54 10 concerning Mrs. Jones' medical course in this case?

11 A No.

12 Q Were you asked to look at whether she had an injury to her
13 pulmonary artery?

14 A Yes.

09:37:05 15 Q Do you have an opinion whether she did or not?

16 A Yes. I think that the lodge -- the fact that a fragment
17 of an IVC filter or any foreign object lodges in a blood
18 vessel like the pulmonary artery is going to create an injury.
19 Blood vessels have very tissue-paper-thin lining, which is
09:37:26 20 intended to be very smooth and pristine, and when it's
21 disturbed by any kind of a foreign object like this, it
22 creates an injury and a reaction.

23 Q And what is that reaction or what can the reaction be?

24 A Well, it can be the formation of scar tissue. It can be
09:37:43 25 inflammation, which itself promotes blood clotting, it

CROSS-EXAMINATION - DAVID GARCIA, M.D.

promotes the aggregation of platelets, which are the sticky cells that help the blood to clot. A whole host of things can happen.

MR. CLARK: Thank you, Doctor.

I think Mr. North is going to have a few questions for you now.

THE COURT: All right. Cross-examination?

MR. NORTH: Yes, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. NORTH:

Q Good morning, Dr. Garcia.

A Good morning.

Q I believe you told us earlier that you charge for your work as an expert witness \$5,000 a day when you're testifying?

A I did.

Q And for how many days will you be charging the plaintiff's attorneys for your work appearing here this week?

A Two days.

Q So \$10,000 for the week?

A Yes.

Q Now, you have been involved not only in this litigation, but in litigation involving Cook Medical Company and their filters; correct?

A I have.

Q And you have been an expert for some of these same

CROSS-EXAMINATION - DAVID GARCIA, M.D.

09:38:45 1 plaintiffs' attorneys in that litigation; is that correct?

2 A I have a vague understanding that there is some overlap in
3 the attorneys in the two cases, but I wouldn't be able to say
4 specifics about that.

09:38:56 5 Q And you have given opinions on behalf of the plaintiffs in
6 that litigation --

7 A I have indeed.

8 Q And you issued an expert report in that litigation;
9 correct?

09:39:05 10 A Yes.

11 Q And, in fact, you gave your deposition in this particular
12 litigation last summer, on July 21, 2017; correct?

13 A Yes.

14 Q And the very following day, with the same attorney
09:39:23 15 assisting you, you gave a deposition in the Cook litigation;
16 correct?

17 A I believe there was -- there were two attorneys there
18 present for Bard and one for Cook, but there was some overlap,
19 yes.

09:39:37 20 Q And you were represented or had the same plaintiffs'
21 attorney with you at both depositions; correct?

22 A Yes.

23 Q And the opinions that you have offered here today are
24 similar to the opinions you've offered against Cook in that
09:39:50 25 litigation; correct?

CROSS-EXAMINATION - DAVID GARCIA, M.D.

09:39:51 1 A Yes.

2 Q Now, you gave some opinions about when you believe the use
3 of IVC filters is appropriate. You still use or recommend the
4 implant of IVC filters on some occasions; correct.

09:40:17 5 A In rare occasions, yes.

6 Q And I believe you told us the scenario where you would
7 recommend an IVC filter be implanted is when someone had a DVT
8 and within a month of a bleeding incident or needing surgery;
9 correct?

09:40:35 10 A That's right.

11 Q And that's exactly the situation that Ms. Jones was in
12 when she received her filter; correct?

13 A Yes.

14 Q In fact, she had a DVT during a time she was being
09:40:47 15 hospitalized for gastric bleeding?

16 A Correct.

17 Q And two or three days after she had the filter implanted,
18 she had to undergo gastric surgery; correct?

19 A Correct.

09:40:58 20 Q And she is exactly the sort of patient that, in your
21 practice, you would recommend a filter be implanted in;
22 correct?

23 A That's right.

24 Q Now, on direct examination and the questions asked by
09:41:27 25 Mr. Clark, you discussed the two PREPIC studies; correct?

CROSS-EXAMINATION - DAVID GARCIA, M.D.

09:41:31 1 A Yes.

2 Q And both of those studies were performed in France?

3 A They were.

4 Q And Bard filters were not utilized in either one of the

09:41:37 5 PREPIC studies; correct?

6 A Correct.

7 Q And PREPIC1 involved only permanent filters?

8 A Correct.

9 Q And PREPIC2 involved only filters manufactured by a single

09:41:53 10 company called ALN; correct?

11 A Yes.

12 Q And patients were excluded from those studies if they were

13 contraindicated for anticoagulant therapy; correct?

14 A That's right.

09:42:15 15 Q So that would be a patient like Ms. Jones would not

16 qualify for those studies.

17 A Indeed. It would be unethical to include patients like

18 that in the judgment of many physicians in a randomized

19 control trial.

09:42:38 20 Q And you are aware that the FDA has cleared filters for use

21 in this country for patients who are either contraindicated

22 for anticoagulants or who have had a situation where

23 anticoagulants have failed to work in them; correct?

24 A I'm aware of that.

09:42:54 25 Q And both of those classes of patients for whom filters

CROSS-EXAMINATION - DAVID GARCIA, M.D.

1 have been cleared by the FDA were not part of these PREPIC
2 studies; correct?

3 A Correct.

4 Q Now, you testified on direct about some of your opinions
5 about the efficacy or effectiveness of filters; correct?

6 A Yes.

7 Q But you have actually published literature yourself noting
8 that filters can be effective; correct?

9 A Well, I'm sure I've said something like that there may be
10 situations where they have a benefit that justifies their
11 risks.

12 MR. NORTH: Could we pull up what's been marked as
13 impeachment Exhibit 5, please.

14 BY MR. NORTH:

15 Q Dr. Garcia, do you recognize this medical article?

16 A I do.

17 Q And I believe you told us in response to one of
18 Mr. Clark's questions that you had published one article that
19 focused on IVC filters with some colleagues; correct?

20 A Correct.

21 Q And this is that article, isn't it?

22 A It is.

23 Q And this was published as recently as 2014?

24 A Indeed.

25 Q And you are listed as one of the authors.

CROSS-EXAMINATION - DAVID GARCIA, M.D.

09:44:27 1 A Yes.

2 Q And what publication or journal was this published in?

3 A Thrombosis and Haemostasis.

4 Q And do you consider that to be a reliable journal?

09:44:39 5 A I do.

6 Q Was this article peer reviewed?

7 A It was.

8 Q If you would look in the first paragraph on the first

9 column, about halfway down. In this article, you and your

09:44:51 10 colleagues stated the following: In the presence of major

11 contraindications to anticoagulant treatment, including

12 bleeding complications during antithrombotic treatment,

13 interruption of the inferior vena cava, IVC, with a filter may

14 prevent life-threatening pulmonary embolism. Correct?

09:45:16 15 A Indeed. And I would highlight the use of the word "may."

16 Q But you published that, you and your colleagues, in the

17 medical literature four years ago; correct?

18 A Yes, we did.

19 MR. NORTH: And if we can look on page 623.

09:45:36 20 BY MR. NORTH:

21 Q You and your colleagues included a summary table of the

22 questions, experts' opinions, and recommendations; correct?

23 A Yes.

24 Q And under question 2 -- or it says: Question 2, are vena

09:45:53 25 cava filters able to reduce the incidence of recurrence of PE

CROSS-EXAMINATION - DAVID GARCIA, M.D.

09:45:59 1 in patience with acute VTE? Correct?

2 A Yes.

3 Q And just so we know, what is VTE?

4 A Oh. That's a term, it stands for venous thromboembolism.

09:46:10 5 And it just intends to encompass both deep vein thrombosis and
6 pulmonary embolism as one disease.

7 Q So the question was basically whether IVC filters are able
8 to reduce the incidence of recurrent PE in people who have had
9 DVTs; correct?

09:46:28 10 A Yes.

11 Q And your answer on behalf of and you your colleagues was
12 the following: Compared to anticoagulation therapy alone,
13 there is evidence that IVC filter placement reduces the short
14 and, to a lesser extent, long-term risk of recurrent PE.

09:46:47 15 Correct?

16 A Yes.

17 Q And so four years ago, in a respected peer-reviewed
18 medical journal, you and your colleagues published an article
19 saying that there is evidence that IVC filters work; correct?

09:46:59 20 A Yes. And I don't think that is inconsistent with anything
21 I've said before.

22 Q In this case you have not offered any opinions as to -- or
23 any criticisms of Ms. Jones' doctors in deciding to implant
24 the filter; correct?

09:47:28 25 A Correct.

CROSS-EXAMINATION - DAVID GARCIA, M.D.

Q And, in fact, you have told us that she is precisely the sort of patient that you personally would recommend a filter for.

A Yes.

Q Now, you have talked about the impact or your concerns about the strut of the filter that remains in Ms. Jones; correct?

A I have.

Q As a part of your work in this case, you have not looked at any of the X-rays or CT scans or radiographic imaging, have you?

A Correct.

Q And so you have not looked at any of the imaging that is available to doctors that would show where the strut is located, what position, and where it stands; correct?

A Sir, I'm not a radiologist. And I've read the report of the images and learned everything I need to know about the strut and its location from that.

Q But you have not looked at the actual --

A But I have not looked at the original images.

Q And you have not looked at the images over time to see whether that strut has remained in a stable location?

A No, I've not.

Q Now, in testifying that you believe there is a risk that the strut could cause a clot to develop in the future, you

REDIRECT EXAMINATION - DAVID GARCIA, M.D.

09:48:49 1 have relied upon the PREPIC article; correct?

2 A I guess in the sense that the PREPIC article -- I would
3 say both PREPIC studies provide evidence that filters
4 themselves cause clotting, whether it be in the form of leg
09:49:09 5 DVT or vena caval thrombosis, yes, I have.

6 Q But those articles concern the entire filter. They did
7 not involve a situation where one small fragment of a filter
8 was producing a clot; correct?

9 A That's right. Unfortunately, we don't have any large
09:49:32 10 follow-up studies that I know of of patients with a fragment.

11 Q So, as you sit here today, you are unaware of any medical
12 study that would indicate that there is a risk of clot
13 development from an individual fragment retained in the
14 pulmonary artery?

09:49:50 15 A I am not aware of any such study, nor am I aware of any
16 study to the contrary.

17 MR. NORTH: Thank you, doctor. That's all I have.

18 THE COURT: Any redirect?

19 MR. CLARK: Yes, Your Honor.

R E D I R E C T E X A M I N A T I O N

09:50:01 20 BY MR. CLARK:
21

22 Q Doctor, in terms of your compensation, are you taking time
23 away from your clinical practice to be here with us today?

24 A Oh, yes. Well, by definition, I'm either taking time away
09:50:17 25 from my normal job, if you will, which includes clinical

REDIRECT EXAMINATION - DAVID GARCIA, M.D.

09:50:20 1 practice, research, teaching, or I'm ultimately taking time
2 away from my weekends and vacation. But I'm giving up one or
3 the other.

4 Q And in terms of you were asked some questions about
09:50:32 5 offering opinions that are identical in some respects with the
6 Cook filter litigation. Do you remember those questions?

7 A Yes.

8 Q Now, are your opinions related to IVC filters in general,
9 or are they specific to a particular device?

09:50:45 10 A They're not specific to any particular device. I don't
11 know of any high-quality comparisons between device types. So
12 the only evidence we have to rely on is extrapolated evidence
13 from all filters.

14 Q And based on that extrapolated evidence, you have similar
09:51:04 15 opinions in both cases?

16 A I do.

17 Q Now, you were asked questions about that you would make a
18 recommendation for Mrs. Jones to have an IVC filter placed,
19 given her medical condition at the time it was placed. Do you
09:51:16 20 remember that?

21 A Yes.

22 Q Would there be a time limitation on how long that filter
23 should be placed, in your opinion, based on what we now know?

24 A Yes. Indeed, the recommendation I would make is that the
09:51:30 25 filter be removed as soon as a patient like Mrs. Jones could

REDIRECT EXAMINATION - DAVID GARCIA, M.D.

09:51:34 1 safely receive anticoagulation therapy.

2 MR. CLARK: Could I ask defendants to publish -- not
3 publish, I'm sorry, show Dr. Garcia the PREPIC file, that
4 table.

09:51:56 5 BY MR. CLARK:

6 Q Doctor, you were asked some questions about this article
7 by Mr. North.

8 A Yes.

9 Q And, again, to emphasize, you're talking about that there
09:52:04 10 could be a short-term benefit; correct?

11 A Right. So what we say is that there is evidence that IVC
12 filter placement reduces the short-term risk of recurrent PE.
13 But we didn't say there's high quality evidence of that. We
14 very intentionally said there is evidence.

09:52:28 15 Q And if you could look at question number 1, are vena cava
16 filters able to reduce mortality in patients with acute VTE,
17 what does it say under number 1?

18 A There's no evidence to support the hypothesis that IVC
19 filters reduce the death from acute venous thromboembolism.

09:52:50 20 Q Is that consistent with the opinions you've offered this
21 morning?

22 A It is.

23 Q And, again, you are not a radiologist; right?

24 A Correct.

09:52:55 25 Q In your practice, if there were radiographs that had to be

REDIRECT EXAMINATION - DAVID GARCIA, M.D.

09:52:58 1 reviewed, would you personally review them in your clinical
2 practice?

3 A Very rarely. If I have -- there are some situations where
4 I may go review them with a radiologist. But I almost never
09:53:06 5 review images independently, because I don't feel trained to
6 do so.

7 Q And would you always defer to a radiologist in terms of
8 evaluating what was shown in a radiograph?

9 A Absolutely. Which is why I tend to mostly read the
09:53:18 10 reports, the detailed reports that radiologists provide,
11 rather than drawing conclusions myself from the films.

12 Q Thank you, Doctor. I have no further questions.

13 THE COURT: All right. Thank you. You can step
14 down.

09:53:42 15 MR. CLARK: Your Honor, at this time the plaintiff
16 would call Carol Vierling via video deposition. Plaintiff
17 would like to move into evidence trial Exhibit 2149, which is
18 deposition Exhibit 231.

19 THE COURT: Just that one exhibit?

09:54:09 20 MR. CLARK: Just that one exhibit, Your Honor.

21 THE COURT: Any objection to 2149?

22 MS. HELM: No, Your Honor.

23 THE COURT: All right. That exhibit is admitted.

24 (Exhibit 2149 admitted.)

09:54:16 25 MR. CLARK: And, Your Honor, as we discussed, we have

REDIRECT EXAMINATION - DAVID GARCIA, M.D.

1 prepared a conversion table for the convenience of the jury.

2 THE COURT: Just for this witness?

3 MR. CLARK: Just for this witness.

4 THE COURT: Well, the only exhibit that is going to
5 be shown is 231.

6 MR. CLARK: Unnecessary?

7 THE COURT: I don't think it's necessary in this.

8 What we talked about, ladies and gentlemen, is if
9 you're shown a deposition where there's ten different
10 exhibits, for you to understand what trial exhibit is, we'll
11 give you a little table that says the deposition number
12 they're referring to equals trial exhibit such and such so you
13 can at least track that somewhat. But I think with just one
14 exhibit we don't need that.

15 MR. CLARK: Fair enough, Your Honor.

16 May I be permitted to read the background summary for
17 Carol Vierling?

18 THE COURT: Yes, please.

19 MR. CLARK: Carol Vierling graduated from Indiana
20 University in 1981 with a degree in nursing, and received an
21 MBA from Mercer University in 1998.

22 From 1992 to 2002, she was the director of regulatory
23 affairs for C.R. Bard. In this role, Ms. Vierling was
24 responsible for developing and implementing regulatory
25 strategies for Bard's peripheral vascular -- sorry, peripheral

DIRECT EXAMINATION - CHAD MODRA

09:55:20 1 vascular devices, including its IVC filters.

2 Since leaving Bard in 2002, Ms. Vierling has
3 continued to work in regulatory affairs in the medical device
4 industry.

09:55:41 5 (Video testimony of Carol Vierling played.)

6 MR. O'CONNOR: Your Honor, we call Chad Modra,
7 please.

8 THE COURT: All right.

9 THE COURTROOM DEPUTY: Mr. Modra, if you would please
10:19:32 10 come forward, raise your right hand.

11 **CHAD MODRA,**

12 called as a witness herein, after having been first duly sworn
13 or affirmed, was examined and testified as follows:

14 MR. O'CONNOR: May I proceed, Your Honor?

10:20:04 15 THE COURT: You may.

D I R E C T E X A M I N A T I O N

16
17 BY MR. O'CONNOR:

18 Q Good morning, Mr. Modra. Thank you for coming.

19 A Good morning.

10:20:09 20 Q Would you state your full name, please.

21 A Chad Michael Modra.

22 Q Mr. Modra, do you still work for Bard?

23 A I do.

24 Q What is your position now?

10:20:17 25 A I'm the continuous improvement leader.

DIRECT EXAMINATION - CHAD MODRA

10:20:20 1 Q Pardon me?

2 A Continuous improvement leader.

3 Q Do you work in Tempe, Arizona?

4 A I live in Phoenix, but I work out of the Murray Hill,
10:20:28 5 New Jersey, office.

6 Q And how long have you been doing that?

7 A Approximately two years.

8 Q But your residence is here in Arizona?

9 A That's correct.

10:20:37 10 Q Mr. Modra, at one time you were the vice president of
11 quality assurance at Bard Peripheral Vascular?

12 A Yes, that's correct.

13 Q And tell the jury what period of time you held that
14 position, please.

10:20:49 15 A The spring of 2011 through the end of 2015. So
16 December 2015.

17 Q And, Mr. Modra, in that capacity, you oversaw quality
18 assurance, field assurance, and other departments?

19 A That's correct.

10:21:09 20 Q Your responsibilities included post market surveillance?

21 A Yes.

22 Q And you oversaw the regulatory obligations of Bard in
23 terms of handling Complaint Record Detail Reports and MDRs.
24 True?

10:21:24 25 A That's correct.

DIRECT EXAMINATION - CHAD MODRA

10:21:25 1 Q MDRs are what?

2 A Medical device reports.

3 Q And you have also been produced in various depositions as
4 the person most knowledgeable about how complaints are handled
10:21:39 5 within Bard; correct?

6 A Within BPV, that's correct.

7 Q Thank you for that clarification. And let's just you and
8 I clarify that for the jury.

9 There's different parts of Bard. Bard Peripheral
10:21:54 10 Vascular?

11 A That's correct.

12 Q Thank you for helping me out on that.

13 And Bard Peripheral Vascular is located here in
14 Tempe, Arizona?

10:22:00 15 A That's correct.

16 Q And among the devices that happened in Tempe, Arizona,
17 were the IVC filters; correct?

18 A Yes.

19 Q And you are knowledgeable about IVC filters as well;
10:22:10 20 correct?

21 A To a certain extent, yes.

22 Q And in terms of complaints, Bard was responsible to
23 investigate every type of complaint that came to it
24 regarding -- we'll just stay with filters today. True?

10:22:28 25 A Correct.

DIRECT EXAMINATION - CHAD MODRA

10:22:29 1 Q And as I understand it, there were sources that Bard would
2 receive complaints from that would include doctors, sales
3 representatives, and even the medical literature?

4 A Correct. Primarily sales reps, but other sources as well.

10:22:45 5 Q The primary source was the sales representatives of Bard?

6 A Yes.

7 Q And sales representatives had ongoing continuous contact
8 with doctors; correct?

9 A As part of their normal jobs; correct.

10:22:59 10 Q And so sales representatives would develop relationships
11 with doctors who would use Bard filters for their patients;
12 right?

13 A Yes. They would -- they would speak to them as frequently
14 as they could.

10:23:14 15 Q And just to be clear, if a doctor had a problem with a
16 filter, what you knew was that frequently that doctor would
17 contact the sales representative, who then would report it to
18 somebody in your department; correct?

19 A Depending on the event, when they see them next time they
10:23:31 20 would note the event, share information.

21 Q Regardless, that would initiate the complaint handling
22 processes within field assurance at Bard Peripheral Vascular.
23 True?

24 A True. Once we become aware of it, that's correct.

10:23:48 25 Q And from that information, there would be investigations

DIRECT EXAMINATION - CHAD MODRA

10:23:53 1 done with Bard; correct?

2 A We'd go through a standard process to investigate each
3 one; correct.

4 Q And it was important for Bard to be as accurate as
10:24:01 5 possible and -- in the investigation to learn all the
6 information, because that would eventually go into various
7 reports. True?

8 A Correct.

9 Q And Bard sought to obtain information that was reliable
10:24:16 10 that would go into the reports that could eventually be
11 reported to the FDA. Fair?

12 A As reliable as we could. I mean, we get information
13 provided to us, and then have to try to ver- -- to confirm
14 that what they're reporting to us is true.

10:24:34 15 Q I thought you said at your deposition, though, you made it
16 a point to say that there's actually different people that may
17 be involved in a single complaint?

18 A There's three people that are involved in, one, taking the
19 information, but then making sure that we're filling out all
10:24:46 20 the fields in the record, and then making sure there aren't
21 any typos, incorrect items recorded in there.

22 Q Since 2003, complaint investigations at Bard had been done
23 and medical device report forms have been completed. Fair?

24 A I'm sorry, what number was that?

10:25:09 25 Q I said 2003. I'm going by your deposition.

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10:25:11 1 Does that sound right?

2 A Could you repeat the question.

3 Q Sure.

4 I read in one of your depositions where you testified

10:25:19 5 that since 2003 there have been complaint investigations going

6 on at Bard?

7 A Of course, yes.

8 Q And those investigations were for, among other purposes,

9 to complete MDR, medical device report, forms?

10:25:37 10 A Correct.

11 Q And it all starts with gathering information and starts

12 with a Complaint Record Detail Report. True?

13 A That takes the narrative that we receive; correct.

14 Q And that's a part of this process that you oversaw?

10:25:52 15 A Yes, that's correct.

16 Q And you are the person who is familiar with this process,

17 starting from how the information comes to Bard and then the

18 development of a Complaint Record Detail Report. True?

19 A True.

10:26:06 20 MR. O'CONNOR: Gay, could you please display for

21 Mr. Modra Exhibit 3270.

22 MS. MENNUTI: 3270?

23 Give me one second, I can pull it up.

24 MR. O'CONNOR: May I approach the witness to keep

10:27:09 25 these things moving with this document?

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1 THE COURT: Not unless you have an exhibit number for
2 it.

3 MR. O'CONNOR: I thought it was 3270.

4 THE COURT: Apparently your team doesn't agree.

5 MS. MENNUTI: No, it is.

6 THE COURT: It is 3270?

7 MR. O'CONNOR: That's my understanding.

8 THE COURT: All right, you can approach the witness
9 with the understanding that is 3270.

10 MR. O'CONNOR: Your Honor, I can identify it for the
11 record, too, what I'm going to approach with. And we can, if
12 necessary, match it up with the correct exhibit.

13 It is a Complaint Record Detail Report, complaint
14 266286, the date created is March 30, 2010.

15 May I show counsel?

16 THE COURT: Yes.

17 MR. O'CONNOR: Is that the number you have?

18 MS. HELM: 3270.

19 MR. O'CONNOR: 3270.

20 Do we have it?

21 Oh, we have it.

22 Thank you, Your Honor.

23 BY MR. O'CONNOR:

24 Q All right, Mr. Modra, we're displaying to you what I've
25 now confirmed, thank goodness, is Exhibit 3270. Do you

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10:28:29 1 recognize this type of a document?

2 A Yes, I do.

3 Q It's a Bard document, correct, as you can tell by the Bard
4 insignia on the upper left-hand corner?

10:28:43 5 A Yes.

6 Q And it's a Complaint Record Detail Report. True?

7 A That's correct.

8 Q And this one happens to be complaint 266286; correct?

9 A Yes.

10:28:57 10 MR. O'CONNOR: And, Gay, if you could please go to
11 page 3 of 5.

12 Well, let's go to page 2 first, and we can just look
13 through it.

14 BY MR. O'CONNOR:

10:29:11 15 Q Mr. Modra, we're looking at page 2.

16 Do you see it there?

17 A I do.

18 Q And that's information that, following Bard's procedures,
19 Bard employees are responsible to collect in the course of an
10:29:29 20 investigation. True?

21 A It includes the narrative of all of the discussions back
22 and forth to whoever we had that was sharing the information
23 with us, that's correct.

24 THE COURT: We're at 10:30, Mr. O'Connor. So we're
10:29:41 25 going to break.

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10:29:42 1 We'll resume, ladies and gentlemen, at 10:45. We'll
2 excuse the jury.

3 (Recess was taken from 10:30 to 10:45. Proceedings
4 resumed in open court with the jury present.)

10:47:43 5 THE COURT: Please be seated.

6 You may continue, Mr. O'Connor.

7 MR. O'CONNOR: Thank you, Your Honor.

8 BY MR. O'CONNOR:

9 Q Thanks for coming back, Mr. Modra.

10:47:51 10 So what we're doing is we're looking at the Complaint
11 Record Detail Report that is marked as Exhibit 3270. And we
12 talked about the event information -- excuse me. We were at
13 page 2 talking about how the information is then generated,
14 recorded, at Bard; is that correct?

10:48:18 15 A That's correct.

16 Q And the investigations are conducted by quality engineers
17 with engineering degrees at Bard; is that right?

18 A They're amongst the team that conducts the investigations.

19 Q And your charge to them was to get as much information as
10:48:34 20 they can about the event; right?

21 A Correct.

22 Q And then employees from research and development and
23 manufacturing were also involved during the investigation.

24 Fair?

10:48:45 25 A That's correct.

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Q And the reason that's important is because these reports are used not only to generate reports for the FDA, but they're also used internally at Bard; correct?

A That's correct.

Q For things like tracking and trending.

A Yes. Each one.

Q If we go to page 3. Are you there? Oh, we aren't there yet.

Page 3 is an event description; correct?

A Event information; correct.

Q By the way, Mr. Modra, back on page 2, the filter we're talking about in this complaint is a G2 filter; right? You can see that in the complaint.

A Yes, it says G2 filter.

Q And then going to number 3, that is the event description, which is a report of the information that has been obtained by your investigative group at Bard. True?

A It's a summary of the event. That's correct.

Q And that summary is used for other reports, including the MDR; correct?

A That or various versions of it; correct.

Q All right. But certainly this is one area that if you want to give a description of the event to an agency or internal department at Bard, or anybody, this is the place you would go. Fair?

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10:50:16 1 A This, as well as the other narrative that we saw on
2 page 2.

3 Q And from this information, Bard would use this
4 information, as we said, to track and trend; correct?

10:50:28 5 A We would use the codes that are present in this file for
6 tracking and trending.

7 Q And you would use this information for various summaries
8 and reports that may go to other departments in Bard. True?

9 A As the basis; correct.

10:50:44 10 MR. O'CONNOR: Your Honor, at this time I would move
11 to admit Exhibit 3270.

12 MR. NORTH: Your Honor, objection. 402, 403, and
13 802.

14 THE COURT: All right. I think this goes to the
10:50:53 15 issue we've been talking about this morning. We're going to
16 need to look at it further, so I'm not going to rule on it
17 now. I'll have to rule after we have further discussions and
18 I look at the cases that were cited.

19 MR. O'CONNOR: All right. Fair enough. Then,
10:51:05 20 Your Honor, in accordance with what we said this morning, I'm
21 going to continue to question along those lines.

22 THE COURT: That's fine.

23 MR. O'CONNOR: All right.

24 Gay, could you put up Exhibit 4515, please.

10:51:22 25 THE COURT: I have a question about where we're going

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10:51:24 1 on that. Why don't we talk for a minute at sidebar just to
2 make sure we're not taking time we don't need to.

3 If you want to stand up for a minute, ladies and
4 gentlemen.

10:51:44 5 (Bench conference as follows:)

6 THE COURT: Mr. O'Connor, by what you just said, are
7 you intending to do this with a whole series of documents?

8 MR. O'CONNOR: No. I have three sets -- well, I now
9 have three sets that will show the complaint event information
10:52:10 10 is identical to what is contained in the monthly report, and I
11 will give him an example of our FRE chart to show him that the
12 same event is also in the monthly report, is also --

13 THE COURT: Okay. I just wanted to make sure you
14 weren't thinking you had to lay foundation document by
10:52:28 15 document for everything you're going to put into a chart.

16 MR. O'CONNOR: No. And I don't want to do more than
17 I have to, but I want to be able to make a record because,
18 depending on how this lands, and let's assume there's a ruling
19 in our favor and that we can prove to you later that we have
10:52:43 20 in our summary events that you deem can be part of the chart,
21 we can work the chart any way, but what I want him to show us
22 and you is that eventually our FRE chart matches the event
23 language here, which is also put in the monthly report, and
24 that we have tracked that same language for our report.

10:53:06 25 THE COURT: Okay, that's fine.

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1 (Bench conference concludes.)

2 THE COURT: Thanks, ladies and gentlemen.

3 BY MR. O'CONNOR:

4 Q Now, Mr. Modra, I'm showing you, displaying, Exhibit 4515
5 just for purposes of you to identify this. And you've seen
6 this type of a report before; correct?

7 A Correct.

8 Q This is a -- entitled -- well, it's known as a monthly
9 management report; correct?

10 A That's the subject; correct.

11 Q And this is an area where people at Bard who were doing
12 complaints knew that there would be summaries of complaints
13 received on a monthly basis that would be provided to people
14 like Mr. Weiland and Mr. Byloos. True?

15 A Correct.

16 MR. O'CONNOR: And if we go, Gay, to page 13 of
17 Exhibit 4515.

18 BY MR. O'CONNOR:

19 Q Mr. Modra, if you look at the second entry there, do you
20 see where it says G2 filter system?

21 A Yes.

22 Q And see the comment section there? And I don't want you
23 to read that aloud, but what I would like you to do is confirm
24 that the language in there is the same identical language that
25 you and I just reviewed in the event description in the

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10:54:53 1 complaint file.

2 A I didn't commit the other one to memory, but --

3 MR. O'CONNOR: Your Honor, I can help Mr. Modra and
4 approach with the language in this.

10:55:06 5 THE COURT: That's fine. Which exhibit are you going
6 to show him?

7 MR. O'CONNOR: 3270.

8 BY MR. O'CONNOR:

9 Q And, Mr. Modra, what I'm going to ask you to do is look at
10:55:13 10 page 3. And just so you know, Mr. Modra, I have put a Post-it
11 there.

12 A Okay.

13 MR. O'CONNOR: May I approach him directly?

14 THE COURT: Yes.

10:55:34 15 THE WITNESS: There's a line over -- okay. Thank
16 you.

17 BY MR. O'CONNOR:

18 Q I'm sorry?

19 A It's the same as the first portion.

10:56:10 20 MR. O'CONNOR: May I approach to get my exhibit back?

21 THE COURT: Yes.

22 MR. O'CONNOR: Thank you, Mr. Modra.

23 Your Honor, subject to the Court's order, I would
24 move at this time for the admission of Exhibit 4515.

10:56:29 25 THE COURT: All right. My response is the same.

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10:56:30 1 We'll need to deal with that when we --

2 MR. O'CONNOR: Your Honor, I just want to make sure I
3 have sufficiently identified the pages for the record and we
4 know what we need to discuss later. I can identify it again
10:56:43 5 in this page. Where I was looking is 4515. Excuse me.

6 THE COURT: I think you said in the record you looked
7 at page 13 --

8 MR. O'CONNOR: Yeah, page 13.

9 THE COURT: -- of that document.

10:57:01 10 MR. O'CONNOR: Thank you.

11 BY MR. O'CONNOR:

12 Q Mr. Modra, this is not going to be the most exciting next
13 few minutes, but I've got to plug through just so we can talk
14 about a couple more examples of complaints. Okay?

10:57:16 15 A Absolutely.

16 Q But one thing I think that we did just illustrate, you and
17 I, is that information that we saw from the complaint file
18 under the complaint event description is language that's used
19 by Bard for other purposes, including summarizing complaints
10:57:38 20 to provide to people who need to know within Bard. True?

21 A True. And it is my experience that the comments in that
22 section may match, but sometimes they're summarized even
23 further to smooth out the language for the report.

24 Q But my point, so you and I are on the same page, you can
10:57:59 25 go to the complaint file and you can go to the MDR, you can

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1 find that language, and you have a system, a data system, at
2 Bard where you can match that up, summarize it, and do all
3 sorts of things with it, including setting up summary reports
4 for management. Fair?

5 A True, but I'd have to verify that this actually was the
6 language used in the MDR. I don't know if that's true.

7 Q All right. But we did just match up where it was
8 identical to the complaint; correct?

9 A That portion of the complaint; correct.

10 Q And I think from the complaint it does go to the MDR. Is
11 that fair?

12 A Narrative of that; correct.

13 Q All right.

14 MR. O'CONNOR: Gay, would you put up Exhibit 45 --
15 excuse me. 3262.

16 BY MR. O'CONNOR:

17 Q And, Mr. Modra, I'm looking at 3262. These are -- were
18 documents produced by Bard. And do you recognize this as
19 being an MDR file?

20 A It says MDR on it, so. I'm not familiar with this one,
21 but, yes.

22 Q It would not be unusual for you, in your position, to go
23 to MDR reports to look on your data or whatever format it was
24 in when you were the vice president. True?

25 A Typically electronic, yes, because I would ask for the

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10:59:46 1 electronic from the database.

2 Q Thank you.

3 MR. O'CONNOR: And if we go to the first page, the
4 next page over, Gay, please.

11:00:01 5 BY MR. O'CONNOR:

6 Q There you see this is the Bard Complaint Record Detail
7 Report.

8 Do you see that?

9 A I do.

11:00:09 10 Q And in there, there is a short description. Right up
11 there.

12 Do you see Short Description?

13 A Yes.

14 Q And that's one way that you shorthand and follow codes
11:00:22 15 that identify what happened and what you were investigating to
16 a filter; correct?

17 A Correct.

18 Q And that could include a number of things, including limb
19 detachment, fracture, tilt, perforation. It's a way to
11:00:39 20 identify the failure that's the subject of the complaint file.
21 Fair?

22 A It's the way to identify, short version; correct.

23 Q And then your team goes about gathering the information.

24 MR. O'CONNOR: If we can go to page 3.
25

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11:00:59 1 BY MR. O'CONNOR:

2 Q That information that gathers will include communicating
3 with people involved such as doctors, also getting medical
4 records and radiographs imaging; correct?

11:01:16 5 A Yes. They ask -- sorry. They ask a series of questions
6 to try to get more information about the event.

7 Q And when you look at Exhibit 3262 at page 3, this does
8 provide an example of how complaints were generated and
9 recorded within Bard; correct?

11:01:35 10 A Yes.

11 Q Thank you.

12 MR. O'CONNOR: And then if you go to page 4, Gay,
13 please.

14 BY MR. O'CONNOR:

11:01:49 15 Q And there is the description that is taken from the
16 investigation; correct? Beginning with the words "It was
17 reported."

18 Do you see that?

19 A I'm looking for it.

11:02:06 20 Q Should be page 4 of 6.

21 A Sorry, there was a different page being shown.

22 Q Would you like us to highlight what I'm referring to?

23 A I can see it now. Correct.

24 Q And am I correct that's the information, how it's written
11:02:20 25 in there, that may be the form that can be used for other

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11:02:25 1 reports, including MDRs and reports or summaries to corporate?

2 A Correct. Typically it starts with "it was reported"
3 because events. That's all we have.

4 Q Just going back, when we see the word "detachment" in a
11:02:41 5 complaint record, for purposes of understanding what we mean
6 or what was meant, detachment is a fracture; correct?

7 A By another term; correct.

8 Q So if somebody were -- an outsider were to look at a
9 complaint report, wanted to know what happened, they could
11:02:58 10 find the type of filter; correct? And they could also go on
11 and find out what was the issue with the filter, and if they
12 were to see "limb detachment," that would be fracture;
13 correct?

14 A The code that's used there is detachment, because it's
11:03:16 15 used across multiple types of products.

16 Q To include fracture of a filter.

17 A Correct. Fracture would be a more specific term related
18 to filters versus another product.

19 Q When you see "detachment" for a filter, that means
11:03:30 20 fracture; right?

21 A Typically, yes.

22 Q Thank you, sir.

23 And then, again, page 4 of 6, I think you confirmed
24 is the statement that is used for other documents and
11:03:41 25 summaries. True?

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11:03:44 1 A As the basis for it. Sometimes there's additional
2 information provided with that.

3 Q And if you could just look at that where it starts out "It
4 was reported that upon examination."

11:03:53 5 Do you see that?

6 A Yes.

7 MR. O'CONNOR: And then, Gay, if you would go to --
8 I've got it as 3662.022.

9 MS. MENNUTI: I'm sorry, can you say that again.

11:04:12 10 (Mr. O'Connor and Ms. Mennuti confer.)

11 MR. O'CONNOR: And, Gay if you could go right to the
12 box, box 5, and highlight that for Mr. Modra, please.

13 BY MR. O'CONNOR:

14 Q First of all, Mr. Modra, I should have you identify what
11:04:41 15 we're looking at. It's a document titled MedWatch and it's an
16 FDA form; is that correct?

17 A That's correct.

18 Q And that is the information that will eventually be
19 comprised as part of a medical device report; right?

11:04:55 20 A That's correct.

21 Q And medical device reports, there's also a responsibility
22 where you have to characterize them as either serious injury
23 or malfunction; right?

24 A That's correct.

11:05:05 25 Q And Bard -- excuse me, the FDA relies on you folks at Bard

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11:05:11 1 to be accurate in how you characterize the complaints and how
2 you describe them. Fair?

3 A That's correct.

4 Q And so your job as the vice president was to make sure

11:05:21 5 that the people under you were following that directive to be
6 as accurate and thorough as possible.

7 A That's correct.

8 Q Thank you.

9 And here you'll see, again, under the MedWatch form,
11:05:38 10 FDA form, another description of the event or problem. And if
11 you want to compare it to what I just read --

12 MR. O'CONNOR: Judge, if -- Your Honor, if you'll
13 allow me to approach the witness, I can show him the first
14 page he looked at so he can compare the two?

11:05:54 15 THE COURT: Of 3270?

16 MR. O'CONNOR: Yes, sir.

17 THE COURT: You may.

18 MR. O'CONNOR: No, this is 3262 -- this is Exhibit --

19 THE COURT: 3262.

11:06:05 20 MR. O'CONNOR: Yes, sir.

21 THE COURT: Okay. That's fine.

22 MR. O'CONNOR: May I approach?

23 THE COURT: Yes.

24 BY MR. O'CONNOR:

11:06:08 25 Q So here, Mr. Modra.

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11:06:44 1 A They're the same.

2 Q Why don't you hold on to it a second.

3 MR. O'CONNOR: At this time, Your Honor, I would move
4 for admission of Exhibit 3262, with the understanding of what
11:06:54 5 your ruling is.

6 THE COURT: All right. Same ruling. I'll deal with
7 that after we've talked through the rest of the issues.

8 MR. O'CONNOR: Thank you.

9 Gay, can you put up Exhibit 4515, please.

11:07:06 10 BY MR. O'CONNOR:

11 Q Mr. Modra, again, can you identify 4515?

12 A It's an example of a monthly management report.

13 Q And it's dated April 8, 2010; correct?

14 A Correct.

11:07:26 15 Q And, again, this, as we described -- discussed in the
16 prior exhibit, is an area where, based upon what the people
17 under you do by way of describing an event, can be used for
18 reports and summaries that go to other departments in Bard.
19 True?

11:07:45 20 A True.

21 MR. O'CONNOR: And, Gay, if you would go to page 12.

22 And, Gay, highlight the second one down, please.

23 BY MR. O'CONNOR:

24 Q Mr. Modra, what we're looking at is a chart, and what I've
11:08:08 25 highlighted -- what we have highlighted for you begins -- it

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11:08:11 1 talks about the G2 filter system.

2 Do you see that? Femoral?

3 A Femoral; correct.

4 Q And then for the description of the event it says

11:08:18 5 "detachment of component's filter limbs."

6 Do you see that?

7 A I do.

8 Q And then to the right is a comment section.

9 Do you see that?

11:08:29 10 A Yes.

11 Q And, sir, I would just ask you to read that comment and
12 compare it to what you just read and confirm that they're both
13 accurate so that we can go on with the process of showing how
14 these reports are used internally and for the FDA.

11:09:17 15 A They're not exactly the same.

16 Q But do they basically contain the same substance and
17 content?

18 A Yes. That was sort of my point, is the person putting
19 these in here would put that information, but then she would
11:09:32 20 use things within the file to summarize that for the report.

21 Q But is it fair to say that what's described -- fair to say
22 that what's described in the monthly report, Exhibit 4515, is
23 what is described in the event report that I just showed you.
24 Fair?

11:09:47 25 A Generally. With a few changes.

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11:09:49 1 Q Same event, though?

2 A Let me make sure.

3 Yes, same event is referenced.

4 MR. O'CONNOR: Thank you.

11:10:02 5 Move to admit 4515.

6 THE COURT: You already have and my ruling's the
7 same.

8 MR. O'CONNOR: Okay. Thank you.

9 Oh. Excuse me. Now, Gay, if you could put up
11:10:19 10 Exhibit 4565 and stay there for --

11 I'm going to have him make one more comparison, so
12 I'm going to show him so he has this exhibit as well,
13 Your Honor --

14 THE COURT: The one that's on the screen?

11:10:34 15 MR. O'CONNOR: 4515. No. This is what he just
16 confirmed.

17 THE COURT: Okay. That's fine.

18 MR. O'CONNOR: May I approach?

19 THE COURT: Yes.

11:10:41 20 BY MR. O'CONNOR:

21 Q This is what you just talked about.

22 A You want this back?

23 Q You might as well keep it. I'm trying to go paperless.

24 If you would go to page 267 and look at that.

11:11:03 25 We're showing it to you right now.

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11:11:06 1 A Okay.

2 Q And can you confirm that what is written in the summary in

3 Exhibit 4565 is the same as the other two documents you just

4 reviewed, please.

11:11:42 5 A The one on the screen is different from this one you just

6 handed to me.

7 Q Pardon me?

8 A I said the one on the screen is different than the one you

9 handed to me.

11:11:50 10 Q Is it the same as the adverse event report?

11 A It is.

12 Q Pardon me?

13 A It is.

14 Q It is?

11:12:03 15 A Yeah.

16 Q So all three of the documents you've looked at, you agree

17 all describe the same event?

18 A All -- the event number references -- is referenced

19 throughout. That's correct.

11:12:15 20 Q The descriptions contain the same facts.

21 A There is one difference, but generally are all filter

22 related and reference that same event.

23 Q Same -- represent the same event, but all substantially

24 similar in their descriptions?

11:12:31 25 A Not exactly the same description, but yes.

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11:12:33 1 Q You would agree with that?

2 A With some editorial changes, yes. Because they aren't
3 exactly the same.

4 Q What would you change?

11:12:46 5 A The language that is used, all the wording in here on the
6 screen is not the same as what is contained in this management
7 report.

8 Q But substantially similar in describing the same event?

9 A It describes the same event, that's correct.

11:12:58 10 MR. O'CONNOR: May I approach and I'll get my paper
11 back from him, Mr. Modra?

12 THE COURT: You may.

13 MR. O'CONNOR: If you want to hand me that back.
14 Thanks.

11:13:09 15 Thank you, sir. So much.

16 Your Honor, just so I make a record, we would move at
17 least for the admission of Exhibit 4565, subject to the
18 ruling.

19 THE COURT: Same ruling.

11:13:41 20 MR. O'CONNOR: All right. Let's go to Exhibit 3304,
21 please.

22 BY MR. O'CONNOR:

23 Q 3304 is, again, looks like the jacket for an MDR file; is
24 that right?

11:14:07 25 A The one prepared for you guys; correct.

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11:14:11 1 MR. O'CONNOR: And if we could go to page 3 of 5.
2 And highlight the event description.

3 BY MR. O'CONNOR:

4 Q Mr. Modra, this particular Complaint Record Detail Report
11:14:40 5 number is complaint 282326, and it deals with an Eclipse
6 filter; is that correct?

7 A I can't see where it says what type of filter it is. It
8 says type of procedure is vena cava filter.

9 MR. O'CONNOR: Let's go to page 2, Gay.

11:15:11 10 BY MR. O'CONNOR:

11 Q On the preceding page under Product Information, do you
12 see where it says Eclipse filter?

13 A I do.

14 Q Thank you.

11:15:17 15 MR. O'CONNOR: Gay, could you please go back to the
16 next page we were looking at.

17 And highlight event description.

18 BY MR. O'CONNOR:

19 Q Mr. Modra, what your team would do would be to gather
11:15:46 20 information, correct, and if a filter -- if they learn about a
21 filter fracturing, they would also get as much information as
22 possible from the doctor, the medical records, and the
23 radiographs; correct?

24 A We would go through a series of questions to try to get as
11:16:01 25 much information as we could from the person that contacted

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11:16:04 1 us.

2 Q An important issue with the fracture is whether the
3 fractured limb went to another place in the body. True?

4 A That's correct.

11:16:13 5 Q That's something that has to be investigated and taken
6 seriously by Bard; correct?

7 A Correct.

8 Q And as I understand it in your data system, if you wanted
9 to find out yourself whether a limb fractured and embolized --
11:16:26 10 that's a word you understand; correct?

11 A Correct.

12 Q That means after it breaks it moves through the
13 circulatory system; right?

14 A Correct.

11:16:34 15 Q And if you wanted to find out if a limb went to a lung, or
16 how many times that happened, you could do that at Bard.
17 True?

18 A I'd have to search through the documents, that's correct.

19 Q And what you could do -- you have a basic understanding of
11:16:49 20 anatomy; correct?

21 A I do.

22 Q And you want to make sure the people who work under you do
23 so they know what they're looking at so they can determine
24 when things are serious. True?

11:16:58 25 A Correct.

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11:16:59 1 Q And you understood that if a limb fractured and was in the
2 lung, that meant somehow in the circulatory system it went
3 through the heart; correct?

4 A Correct.

11:17:08 5 Q And the thing that concerns people and is a concern for a
6 medical device company, or should be, is if the limb fractures
7 and embolizes it can go -- and it goes through the heart or
8 stays in the heart or goes into the lung, that can be a
9 dangerous injury. True?

11:17:26 10 A It has the potential to.

11 Q I mean, that's a serious condition and that's why Bard
12 receives that information; correct?

13 A Correct.

14 MR. O'CONNOR: So, if you could, I'd like you to,
11:17:43 15 Gay, highlight the event description.

16 BY MR. O'CONNOR:

17 Q And you see the event description here that involves an
18 Eclipse filter; correct?

19 A Correct.

11:18:12 20 MR. O'CONNOR: And if we go to page 3304.

21 Again, the event description -- wait until we get
22 there.

23 You know what, I'm sorry, Gay.

24 MS. MENNUTI: What page are you on?

11:18:36 25 MR. O'CONNOR: Highlight the event description. I'm

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11:18:38 1 getting ahead of you. I apologize.

2 BY MR. O'CONNOR:

3 Q Now you've read that, sir?

4 A I have.

11:18:51 5 Q All right.

6 MR. O'CONNOR: And then if we go to -- further in the
7 file to the MedWatch form for FDA, to the MedWatch form for
8 FDA as part of this exhibit.

9 I think one more.

11:19:13 10 There you go. Thanks. Good work, Gay.

11 And highlight, Gay, if you would, description of
12 event.

13 BY MR. O'CONNOR:

14 Q And, Mr. Modra, do you agree reading that that that's the
11:19:37 15 same description you just read of the event that is the
16 subject of this investigation we're looking at in
17 Exhibit 3304?

18 A I'd to have compare it again, I'm sorry.

19 MR. O'CONNOR: May I approach?

11:19:53 20 THE COURT: You may.

21 BY MR. O'CONNOR:

22 Q Here you go. That's the part we just looked at.

23 A They're the same.

24 Q So the same information that's written in the Bard
11:20:32 25 complaint investigation is also the information that is

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11:20:36 1 completed into the MedWatch form at Bard; correct?

2 A In this instance, yes.

3 Q And that form is something that Bard sends to the FDA.

4 A We provide that to them; correct.

11:20:49 5 Q And completing that form, like any investigation, it's
6 important to be thorough and accurate. True?

7 A Of course.

8 Q You understand that people in your company rely on these
9 reports to be as accurate as possible; correct?

11:21:03 10 A Correct.

11 Q You understand, of course, the FDA's going to rely on your
12 company to be accurate in reports to the FDA; right?

13 A Correct.

14 Q And as we talked about earlier, let's take a look at --

11:21:16 15 MR. O'CONNOR: And, again, I would move for admission
16 of Exhibit 3304, subject to the ruling, Your Honor.

17 THE COURT: Same ruling.

18 MR. O'CONNOR: And let's go to Exhibit 4519.

19 BY MR. O'CONNOR:

11:21:38 20 Q 4519 is a Bard monthly report of the same type we've
21 looked at just previously, is that correct, Mr. Modra?

22 A Correct.

23 Q And it's dated August 9, 2010.

24 Do you see that?

11:21:53 25 A I do.

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1 Q And, again, this report goes to Mr. Ring, Mr. Weiland, and
2 Mr. Byloos?

3 A It does.

4 Q And who are they?

5 A The former CEO of Bard, COO of Bard, and I'm not sure who
6 Peter Byloos was at the time.

7 Q But you knew who John Weiland was?

8 A Yes.

9 Q Important people.

10 A Of course.

11 MR. O'CONNOR: And let's go to page 14.

12 And, Gay, we're looking at about the fourth down, if
13 you would highlight that for Mr. Modra.

14 BY MR. O'CONNOR:

15 Q And, Mr. Modra, in this report that was given to Mr. Ring
16 and Mr. Weiland, this contains summaries of events. And can
17 you confirm for us today that what you're looking at at
18 page 14 matches and has the same information and is the same
19 report of the other document that I just approached you with,
20 the complaint file, please.

21 A It's the same.

22 Q Thank you.

23 MR. O'CONNOR: And, Gay, if we could go to --

24 I would move to admit 4519, Your Honor, understanding
25 subject to the same order.

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11:23:34 1 THE COURT: Same ruling.

2 MR. O'CONNOR: Thank you, sir.

3 Lets go to Exhibit 4565.

4 BY MR. O'CONNOR:

11:23:46 5 Q And what I'm showing to you is a chart summarizing the
6 adverse events reports and compiling a chart.

7 Can you confirm that the language is substantially
8 similar at page 26 --

9 MR. O'CONNOR: I'm sorry. Excuse me. I think we're
11:24:18 10 going to page 283, Gay.

11 MS. MENNUTI: Page what?

12 MR. O'CONNOR: 283.

13 4565.

14 May I approach, Your Honor, with Exhibit 4565? I can
11:25:27 15 probably show him. I think we're having a hard time getting
16 it up on the screen.

17 THE COURT: It's up. Isn't that it?

18 MR. O'CONNOR: No, that's not it.

19 My notes have it at page 283.

11:25:50 20 I can show him the hard copy.

21 THE COURT: That's fine. Go ahead.

22 BY MR. O'CONNOR:

23 Q This is Exhibit 4565, Mr. Modra, and if you'd look at page
24 283. Right there.

11:26:15 25 A Okay.

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11:26:15 1 Q Are you able to read it?

2 A Yes.

3 Q Same event described?

4 A They're the same.

11:26:51 5 Q And, Mr. Modra, just, again, if, for example, you received
6 a complaint of a patient who had an Eclipse filter fracture
7 and that fracture was found to have embolized up through the
8 vena cava, through her circulatory system, through her heart,
9 and embedded in her pulmonary artery, or her lung, if you
11:27:14 10 wanted to find out how many events you had for all filters
11 since the beginning of the Recovery or any single filter, you
12 could do that in TrackWise; correct?

13 A Correct.

14 Q And that would be a way that Bard could look at what
11:27:30 15 events may be relevant to other events, what events are
16 similar, and get as detailed as Bard would want, depending
17 what they wanted to look at; correct?

18 A You can sort the data a number of different ways based on
19 the fields.

11:27:45 20 Q You can do everything from as general as looking at how
21 many leg fractures did you have over time, true, that were
22 reported to Bard?

23 A Correct.

24 Q I mean, all you do receive are what's reported to you;
11:27:55 25 correct?

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11:27:57 1 A Correct. Or go through literature or --

2 Q If something's reported or documented, Bard should get

3 ahold of that and put it in this database. True?

4 A True. Even if it's anecdotal.

11:28:11 5 Q So if you wanted to find out the reports that Bard had

6 received of fractures since the Recovery through the Eclipse,

7 you can do that; correct?

8 A Correct.

9 Q You have done things like that. True?

11:28:24 10 A Correct.

11 Q If you wanted to find out how many limbs had fractured and

12 wound up in a patient's lung, you could do that; correct?

13 A Correct.

14 Q You could do a compilation of the Recovery all the way

11:28:36 15 through the Eclipse or to the present date. True?

16 A Correct.

17 Q But the only way you get that information is if it's

18 reported to you; right?

19 A Again, if we see it through literature, that's not

11:28:48 20 necessarily reported to us. We may -- we review literature

21 periodically to look for those things proactively.

22 Q But fractures to the lung are something Bard should take

23 seriously; right?

24 A We do take it seriously.

11:29:03 25 Q And you are aware, and we talked about it before, that one

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1 reason Bard may not receive a report is because a patient is
2 asymptomatic and doesn't know he or she has a failed filter;
3 right?

4 A Correct.

11:29:17 5 Q Sometimes what will happen is you'll receive a report
6 because a doctor, while doing a radiographic study on a
7 different issue or condition, sees or observes the fracture in
8 imaging studies; right?

9 A We have had that; correct.

11:29:33 10 Q And that's reported to you; correct?

11 A If they report it to us; correct.

12 Q And whether it's symptomatic or asymptomatic, Bard should
13 take that seriously. True?

14 A We do.

11:29:44 15 Q Because you know that a filter piece that's in a lung,
16 whether a patient knows it's there or not, could evolve into
17 danger.

18 A There's different gradations of severity of that and, per
19 definition of FDA MDRs, we would file them appropriately.

11:30:04 20 Q You're concerned things could change with a foreign body
21 in a patient's body; right?

22 A Yes. You don't know.

23 MR. O'CONNOR: May I approach and get my paper back?

24 THE COURT: Yes.

11:30:24 25 MR. O'CONNOR: One more quickly and we can move to a

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11:30:26 1 different area.

2 Gay, if you would put up Exhibit 3476, please.

3 THE COURT: Mr. O'Connor, are you going to go through
4 the same steps again?

11:30:50 5 MR. O'CONNOR: If you're telling me that it's not
6 necessary --

7 THE COURT: I don't think it's necessary.

8 MR. O'CONNOR: All right, then I won't. Thank you,
9 Your Honor.

11:30:57 10 BY MR. O'CONNOR:

11 Q Mr. Modra, you agree that Bard is responsible to put
12 patient safety first. True?

13 A Correct.

14 Q And as it deals with the FDA, you understand that the FDA
11:31:59 15 operates on an honor system; correct?

16 A Correct.

17 Q Meaning that the FDA expects and relies on companies like
18 Bard to be truthful, to be accurate, and always be honest in
19 dealing with them. True?

11:32:19 20 A True. Honor system, but they do verify.

21 Q Well, if the honor system fails, then the whole system
22 would fail, wouldn't it?

23 A I'm not sure how to answer that.

24 Q Well, the system works if Bard is following its
11:32:35 25 responsibility to be honest and forthright; correct?

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11:32:38 1 A Yes, of course.

2 Q And that means the responsibility of Bard for its filters
3 doesn't end when the filter leaves Bard's hands, does it?

4 A No. Certainly not.

11:32:52 5 Q An important responsibility Bard has is to continue
6 keeping its ear to the ground on what's happening to its
7 filters out there after they're in patients; correct?

8 A Correct.

9 Q And we just talked about one way Bard is required to do
11:33:08 10 that; right?

11 A Yes.

12 Q Part of market surveillance means tracking complaints;
13 right?

14 A Amongst many other things; correct.

11:33:19 15 Q And the reason, among others, that you want to track and
16 follow complaints is to look for trends; correct?

17 A Correct.

18 Q And, also, if you need to advise or warn doctors who are
19 using these filters of problems that you're seeing, that's how
11:33:34 20 the information and how important that responsibility is;

21 correct?

22 A We use that to continually evaluate risk/benefit and the
23 profile of the device; correct.

24 Q Now, these documents that generate into these summarized
11:33:48 25 reports that we saw that go to Mr. Weiland and Mr. Ring, you

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11:33:53 1 have told me before that Bard doesn't share those with
2 doctors; correct?

3 A No.

4 Q And those summary reports that talk about failures and
11:34:05 5 complications, Bard doesn't even share that information with
6 its sales force. True?

7 A Typically, no.

8 Q But Bard knows that the sales force is the base of Bard.
9 They're the ones that interact with the doctors primarily.
11:34:21 10 True?

11 A True.

12 Q And Bard knows that for it to sell its products out there,
13 that it's important that that sales department, that sales
14 force, those sales representatives, have a good, trusting
11:34:36 15 relationship with their doctors who are customers. Fair?

16 A True.

17 Q That makes sense to you; right?

18 A Yeah, it does.

19 Q I mean, you understand that doctors rely on the
11:34:47 20 representatives of Bard to be truthful and accurate with them;
21 correct?

22 A They do.

23 Q I mean, truth and accuracy is the basis of a good
24 relationship. And for Bard, a relationship between the sales
11:35:00 25 force and doctors means the ability to promote its devices.

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11:35:05 1 True?

2 A It has to be true as well as balanced for promotion.

3 Q I understand that. But to my point, you know that doctors
4 do rely on the sales force; correct?

11:35:18 5 A To some extent. But they don't rely only on the sales
6 force to make decisions on that. That would be --

7 Q The sales force is a good way to communicate anything that
8 Bard is aware of to doctors. One way.

9 A It's one way of communicating.

11:35:33 10 Q Thank you.

11 Now, from time to time the FDA can show up at the
12 door at Bard for an inspection and investigation, whatever;
13 right?

14 A They can. Unannounced.

11:35:53 15 Q And one area that the FDA does regulate, as we talked
16 about, are complaints. True?

17 A One area compared with many, many others.

18 Q I -- I understand that. And for right now all I want to
19 do is focus on that.

11:36:10 20 A Correct.

21 Q The FDA expects and relies on Bard to accurately report
22 complaints to the FDA; correct?

23 A They do.

24 Q The FDA expects Bard to be accurate and truthful in how it
11:36:21 25 characterizes complaints that it reports to the FDA. True?

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11:36:25 1 A For everything that's reported to us; correct.

2 Q And the FDA relies on Bard to make sure that when it
3 characterizes events, that it's characterizing them correctly.
4 True?

11:36:41 5 A True.

6 Q And there's two basic labels or descriptions that go with
7 complaints. One is serious injury; correct?

8 A Correct.

9 Q And the other is a malfunction. True?

11:36:54 10 A True. I would actually characterize it as three because
11 some events are not reportable to FDA.

12 Q Okay. But that all is decided right there in the offices
13 of Bard; right?

14 A It's decided on the narrative of the event; correct.

11:37:10 15 Q But, Mr. Modra, so you and I are on the same page, it's
16 people that work at Bard that make these decisions: Serious
17 injury, malfunction, nonreportable. True?

18 A In accordance with the FDA's definitions, true.

19 Q And that is a perfect example of how the FDA relies on the
11:37:29 20 honor system; right?

21 A Correct.

22 Q Bard, they give Bard a big privilege in doing things
23 Bard's way, expecting Bard to be truthful and accurate. Fair?

24 A Yes. They give us the privilege to do it their way, to be
11:37:50 25 truthful and accurate.

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11:37:51 1 Q But they're not there watching you every day, are they?

2 A They're not.

3 Q They're not sitting in that room when people are making
4 decisions as to what is going to be characterized as a serious
11:38:01 5 injury, what's going to be described as a malfunction. True?

6 A True. They provide guidances, regulation to clarify that.

7 Q And then they expect you to do everything you can to be
8 accurate with them. Fair?

9 A True.

11:38:20 10 MR. O'CONNOR: May I approach, Your Honor?

11 THE COURT: Yes. Well, what are you going to
12 approach with?

13 MR. O'CONNOR: About an issue that I think under an
14 order I need to approach about.

11:38:27 15 THE COURT: Oh, you mean over here?

16 MR. O'CONNOR: Yes. I'd like a sidebar.

17 THE COURT: Okay. Well, are you going to be -- we're
18 going with Dr. Modra, Mr. Modra, past the noon hour?

19 MR. O'CONNOR: Could happen.

11:38:39 20 THE COURT: Let's not take the jury's time on this;
21 let's talk about that when we break for lunch.

22 MR. O'CONNOR: But that's where I'm at, where I plan
23 to wrap it up. Can I talk to my lawyer for a moment?

24 THE COURT: Yes, you can talk to your lawyer.

11:38:52 25 MR. O'CONNOR: Thank you.

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11:39:00 1 I got a whole bunch of them.

2 (Counsel confer.)

3 THE COURT: If you want to stand up, ladies and
4 gentlemen, while they're talking, feel free.

11:39:56 5 MR. O'CONNOR: One more area I was planning this
6 morning, the other issue, and then I was going to wrap it up
7 with him.

8 THE COURT: How long will the other area take?

9 MR. O'CONNOR: I think this could take five minutes.

11:40:06 10 THE COURT: Okay, then let's talk.

11 You can stay standing.

12 (Bench conference as follows:)

13 MR. O'CONNOR: Hi.

14 THE COURT: Hi. How are you?

11:40:45 15 MR. O'CONNOR: I want to admit the warning letter in
16 the exact form that we had it in Booker.

17 THE COURT: So meaning only Section 3(A), (B), and
18 (C)?

19 MR. O'CONNOR: Right.

11:40:58 20 THE COURT: Okay. Tell me why you think that should
21 come in.

22 MR. O'CONNOR: Well, it's relevant for a number of
23 issues. In opening statement and the way Bard has taken the
24 position that they are going to start putting up rates they
11:41:12 25 claim are accurate, I think we have a right to show, number

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11:41:15 1 one, they didn't comply with the regulations and the FDA had
2 to come to them because the complaints are part of the way
3 they developed these statistics and trend and track these
4 incidents that they're going to talk about later through this
11:41:32 5 trial.

6 THE COURT: All right.

7 MR. NORTH: Your Honor, I think it's premature. This
8 witness will be back as part of our case in chief. If they
9 believe a door has been opened at that time, he will be here
11:41:45 10 for them to ask about it. But at this point I think it's
11 premature, that no door has been opened to admit this
12 document.

13 It's clearly -- there are major 403 concerns with it,
14 and also I think there's an issue about 402 because virtually
11:42:05 15 all of these complaints were actually submitted to the FDA,
16 the question is just whether they were characterized as a
17 serious injury or malfunction. They were still made part of
18 the MAUDE database regardless how characterized.

19 So it really does -- has, at most, marginal probative
11:42:24 20 value.

21 THE COURT: Okay. Hold on just a minute.

22 The problem I'm having, Mr. O'Connor, is I didn't
23 know this issue was going to come up so I haven't gone back
24 and read the orders and I haven't read my notes on my reasons
11:42:47 25 for admitting it before, and I don't remember them.

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11:42:53 1 MR. O'CONNOR: May I speak for one second?

2 THE COURT: Yeah. Yeah.

3 MR. O'CONNOR: Here's the other reason I think it's
4 important. Because in opening statement, they have made a big
11:43:01 5 issue out of Doris Jones being asymptomatic. And that goes to
6 the issue of how they internally regard these things in terms
7 of malfunction versus serious injury.

8 We're going to present evidence, and I think I've
9 even started the process here, showing that a filter fragment
11:43:21 10 in the lung, in the pulmonary artery, is a serious condition.
11 That's our case. Their case is no harm, no foul.

12 And so I think this is probative of how FDA and the
13 public rely on Bard to recognize what's serious and what's not
14 serious in how they even handle complaints in the first place.

11:43:44 15 THE COURT: Okay. I understand what you've said. I
16 think I need to read the warning letter again and I need to go
17 back and read my orders on it before I can make a ruling on
18 that.

19 MR. O'CONNOR: Your Honor, I think -- I understand.
11:43:58 20 And I understand we have time, and respect that, and I'm
21 trying to do everything I can to move things along in this
22 trial. My problem, of course, is that putting some of these
23 things off when I have the witness here --

24 THE COURT: Well, I know that, but there's nothing I
11:44:14 25 can do about that. I can't say I'll admit it because the

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11:44:17 1 witness is here.

2 MR. O'CONNOR: Do I need to make any more foundation
3 or have I --

4 THE COURT: There's not a foundation issue on this.

11:44:22 5 MR. NORTH: No.

6 THE COURT: It's purely a relevancy and 403 issue.
7 Is that right?

8 MR. NORTH: Right, Your Honor.

9 THE COURT: So you don't have to do anything more
11:44:28 10 with this witness to get this in. I've just got to look back
11 at my previous reasons and decide if I think it's relevant and
12 whether or not 403 bars it. And I can't do that without
13 refreshing my memory.

14 MR. O'CONNOR: I understand that.

11:44:39 15 And just for the record, right now I'm talking about
16 Exhibit 1680, which was the warning letter. Do I need to make
17 any further record on that now?

18 THE COURT: No.

19 Go ahead.

11:44:51 20 MS. REED ZAIC: I want to clarify Mr. Modra is coming
21 back. My understanding is we had to put him on today; we
22 don't have him after this.

23 MR. NORTH: That's not true.

24 THE COURT: Okay, we'll --

11:44:58 25 MS. REED ZAIC: We have time --

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1 THE COURT: I'll also -- I'll also say this: If he
2 comes back -- he is coming back in your case?

3 MR. NORTH: Yes.

4 THE COURT: I'm not going to limit you because it's
5 not within the scope. If there's things on this you need to
6 go back into, then I'll let you do that. So you're not going
7 to get boxed in.

8 MS. REED ZAIC: Thank you.

9 THE COURT: Okay. So I'll look at these issues and
10 then we'll deal with it. It may be before he comes back, if I
11 can rule. If not, when he comes back.

12 (Bench conference concludes.)

13 THE COURT: Thank you, ladies and gentlemen.

14 MR. O'CONNOR: Oh, I'm sorry. Exhibit 2048.

15 BY MR. O'CONNOR:

16 Q Mr. Modra, other documents generated at Bard that Bard
17 uses in its business, in its ordinary course of business, are
18 Failure Investigation Reports; correct?

19 A They were; correct.

20 Q Pardon me?

21 A They were; correct.

22 Q And Failure Investigative Reports are also known as R002
23 history reviews?

24 A That's correct. Typically FIRs, as they're stated, are a
25 subset of the R002 document.

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11:47:27 1 Q All right. I'm showing you Exhibit 2048; correct?

2 A I don't see where that number is.

3 Q Well, what you're looking at, for the record, is
4 Exhibit 2048, and it is failure investigation R002 history
11:47:50 5 review; correct?

6 A Correct.

7 Q And it has a number of tables, including tables describing
8 the G2 and events that happened with the G2; correct?

9 A Correct.

11:48:04 10 Q And also the Recovery filter; correct?

11 A Correct.

12 Q And if we go to -- and this is a document that you're
13 familiar with. True?

14 A In preparing for this.

11:48:25 15 Q Pardon me?

16 A In preparing for this testimony; correct. I'm not sure of
17 its original origin.

18 Q Well, it's a Bard document, and it's a Bard document that
19 also relies on complaint reports; correct?

11:48:40 20 A I'd have to look at those individual reports. It could be
21 for any sorts of reasons why we would conduct an additional
22 investigation.

23 Q Can you tell the jury what a failure investigation is.

24 A In this context, it's something even in addition to
11:49:11 25 what -- the kind of investigation we would have done for that

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1 particular event in a complaint record. We would have gone
2 back and looked at additional records even beyond that single
3 one. Or if it's related to manufacturing, if there was
4 something we noticed in manufacturing we were interested in,
5 we might conduct an additional investigation there to see if
6 it's anything we need to be concerned about.

7 Q And failure investigations are memorialized in these type
8 of reports, R002 history reviews; correct?

9 A In the documents themselves. This looks like a summary.

10 Q Okay.

11 MR. O'CONNOR: Gay, if you could go to page 2 and
12 just scroll slowly so Mr. Modra can familiarize himself with
13 the contents of the report.

14 Or, to expedite it, Your Honor, I can approach the
15 witness with my copy?

16 THE COURT: That's fine.

17 BY MR. O'CONNOR:

18 Q Page through it.

19 A Um-hmm.

20 Okay.

21 Q Do you recognize that?

22 A Generally.

23 Q Do you recognize the form? It's a Bard document that
24 relates to failure investigations, including failures of Bard
25 filters; correct?

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11:51:06 1 A It does.

2 Q And that is another report that relies on people that
3 worked under you in terms of providing complaint information
4 and adverse event information. Fair?

11:51:20 5 A It isn't a standard format or report. It's something --
6 looks like it was summarizing historical events.

7 Q But you understood that that's another area that summaries
8 of your reports that start with your people is also how that
9 information is used in Bard. True?

11:51:38 10 A True.

11 MR. O'CONNOR: May I approach and get the exhibit
12 back, Your Honor?

13 THE COURT: Yes.

14 MR. O'CONNOR: Thank you, sir.

11:51:56 15 I move for admission of 2048, subject, probably, to
16 the same ruling you made before, Your Honor.

17 THE COURT: All right. Same ruling.

18 BY MR. O'CONNOR:

19 Q Mr. Modra, one thing that you did become aware of while
11:52:23 20 you're at Bard is that in filters, there were times where
21 there would be relationships between one failure and another;
22 correct?

23 A They can be reported at the same time.

24 Q I mean, it's not unusual to see tilts accompanied by
11:52:41 25 perforation or accompanied by fracture or migration. Fair?

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11:52:45 1 A True. There may be multiple of those failure events at
2 the same instance.

3 Q And that's something that you and your team at Bard, in
4 addition to complaints, were looking at; correct? More than
11:52:59 5 one failure in any given patient.

6 A Yes. Yes. We track all of the failures and track and
7 trend them regardless of if there's multiples on a single
8 event.

9 Q Understanding that the information that you provided to
11:53:13 10 Bard internally, Bard's choice, could be used for failure
11 investigations; correct?

12 A True.

13 Q Could be used, if Bard so chose, to trend and track
14 events; correct?

11:53:28 15 A We do.

16 Q And if Bard wanted to track a relationship between
17 events -- migration, fracture, embolization -- Bard has the
18 capability to do that; correct?

19 A We have the reports of those. I'd have to understand the
11:53:45 20 scientific nature of those relationships, though.

21 Q And those are internal reports; correct?

22 A I don't know what reports you're referring to.

23 Q You have the capability. That's the point.

24 A We have all the events reported; correct.

11:53:57 25 Q And, certainly, to generate whatever type of report Bard

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11:54:01 1 wanted to do, if it wanted to find out how many types of
2 failure modes are happening that are reported to Bard;
3 correct?

4 A Correct.

11:54:11 5 Q But Bard also knows that there are more failures out there
6 in the population that haven't been reported; correct?

7 A That's typically what is said in the industry.

8 Q In other words, when you do post-market surveillance, you
9 really should be concerned not just about the reports you're
11:54:36 10 receiving, but whether this is happening to patients and maybe
11 the patient doesn't know it or her doctor doesn't know it;
12 right? That should be a concern of Bard's?

13 A Yes. It is.

14 Q In other words, Bard should always be concerned about how
11:54:52 15 many failures are out there that we just don't know about.

16 A Yes. But there's, unfortunately, limited ways to even
17 obtain that information, if at all.

18 Q One reason Bard tracks and trends is so that it can learn
19 whether there's some predictability among failures; correct?

11:55:15 20 A We track and trend to see if there's an increase or
21 decrease in a particular failure mode experience with the
22 device.

23 Q And one reason is because Bard has to be concerned; if
24 it's happened in these many patients, could it happen again.

11:55:33 25 A That's the observed rate versus predictability, and that

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11:55:36 1 would be difficult to do outside of a controlled study.

2 Q And whether it's difficult or not, it's something a
3 medical device company should be concerned about; correct?

4 A We're concerned about it, but it's -- it could be
11:55:50 5 erroneous, highly erroneous, to predict that.

6 Q There could also be patients out there who just don't know
7 they have a failed filter. True?

8 A True.

9 Q You just don't know how many; right?

11:56:03 10 A No.

11 MR. O'CONNOR: That's all I have.

12 THE COURT: All right. Are you going to have any
13 cross on this?

14 MR. NORTH: No, Your Honor. We will reserve our
11:56:11 15 opportunity to question him during our case in chief.

16 THE COURT: Okay. So we'll excuse Mr. Modra for
17 today.

18 Who is your next witness going to be?

19 MR. O'CONNOR: Mr. Carr.

11:56:26 20 THE COURT: Why don't we take him up after the lunch
21 hour.

22 Ladies and gentlemen, we will break until 1 o'clock
23 and resume at that time.

24 (The jury exited the courtroom at 11:57.)

11:57:01 25 THE COURT: Counsel, how much time is allocated to

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11:57:03 1 the video that was shown?

2 MS. HELM: Oh. Your Honor, it's --

3 MR. CLARK: 17 for the plaintiff and six for the
4 defendant.

11:57:16 5 MS. HELM: I agree with that, Your Honor.

6 THE COURT: All right. As of now, plaintiff has used
7 eight hours and eight minutes. Defendant has used two hours
8 and 53 minutes.

9 Mr. North, did you have 403 cases you wanted me to
11:58:22 10 look at during the lunch hour?

11 MR. NORTH: Your Honor, I'm sorry, I misspoke this
12 morning. Those cases are cited in draft -- the brief we
13 provided. It's the *Nelson versus Brunswick* decision of the
14 Ninth Circuit and the *Schwartz versus New Castle Corporation*
11:58:37 15 decision. They're cited in the final paragraph of our bench
16 brief that we filed.

17 THE COURT: All right. Let me ask you this question,
18 Mr. North: It seemed to me that the testimony of Mr. Modra
19 established that the event reports or event descriptions that
11:59:03 20 are included in the initial complaint report which Bard makes
21 an effort to collect as much information as it can --

22 MR. NORTH: Right.

23 THE COURT: -- are carried forward into the monthly
24 management reports and are carried forward into the MedWatch
11:59:20 25 reports that go to the FDA, either verbatim or with close

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11:59:26 1 language to what's in the original complaint report.

2 MR. NORTH: Right.

3 THE COURT: Do you disagree with that?

4 MR. NORTH: No, I do not.

11:59:33 5 THE COURT: And it seemed to me, as well, that that
6 basic description of the event is what's been included by the
7 plaintiff in the 1006 summary.

8 MR. NORTH: I agree with that. The only exception I
9 would make is back to the MDR reports. I believe the
11:59:48 10 description in the MDR reports are usually more abbreviated
11 than we've seen in the actual complaint files and in the
12 management reports. But it's just a summary of the same
13 event.

14 THE COURT: Okay. So the question I have for you is
12:00:07 15 if Bard is taking the event description and, in substance, is
16 communicating it to the FDA, and if some Bard employees are
17 taking that event description and communicating it internally
18 to the COO and CEO, why are those not adoptive admissions?

19 MR. NORTH: Your Honor, I don't believe they should
12:00:33 20 be because they're merely just reports. Nobody's adopting the
21 truth of what was told. Nobody is adopting what is in the
22 medical records. We're merely fulfilling our regulatory
23 function of passing on that information that has been
24 received. Sometimes they are able to verify it. Many times
12:00:55 25 they are not. So how could they possibly be adopting as true

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12:01:01 1 information that they have not been able to verify?

2 THE COURT: Okay. I understand that position.

3 Let me ask you one other question. It seems clear to
4 me from Mr. Modra's testimony that Bard relies upon the event
12:01:16 5 description for purposes of reports to senior management, for
6 purposes of tracking and trending, and for purposes of reports
7 to the FDA. It also seems it seems to me that Mr. Modra
8 established that Bard has a substantial interest in the
9 accuracy of the reports and does what it can to confirm the
12:01:39 10 accuracy.

11 Do you agree with both of those propositions?

12 MR. NORTH: Yes, Your Honor, with the caveat they're
13 not always successful in confirming.

14 For example, I know this from personal experience and
12:01:53 15 observations. With so many of these reports coming in through
16 litigation, basically their only method of corroborating are
17 the plaintiffs' profile forms that are filed.

18 THE COURT: Have you looked at the plaintiff's
19 chart to identify which complaints you think were generated by
12:02:16 20 attorneys rather than by doctors or sales representatives?

21 MR. NORTH: No. I'm not even positive I could do
22 that. I can certainly find out if it's possible over lunch.

23 THE COURT: Well, it seems to me that if I decide
24 that the *Childs* line of cases, well, *Childs* and *MRT*, only
12:02:35 25 requires that the company rely upon it and have a substantial

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12:02:39 1 interest in its accuracy, that what is the foundation that's
2 been laid overcomes the hearsay problem if that's all that's
3 required.

4 I know you don't agree with my relying on that line,
12:02:53 5 but do you agree that under my reading of *Childs* there's not
6 some flaw in the foundation here?

7 MR. NORTH: I respectfully don't agree with the
8 reading of *Childs*. But based on your reading as I understand
9 it, I would agree with that, Your Honor.

12:03:07 10 THE COURT: Okay.

11 The other two arguments I need to look at -- I'll
12 think more about that. I want to look at *Childs* again. But
13 the other two arguments, one is the substantial equivalence
14 argument that you've made and the other is the 403 argument
12:03:26 15 based on *Nelson* and *Schwartz*, so I'll look at those cases.

16 I'll not rule until I give plaintiff an opportunity
17 to argue. I don't want to argue it now, I just want to make
18 sure I understand the defendants' position.

19 MR. NORTH: If I could just say one more thing. I
12:03:38 20 also don't believe -- or do believe, as you pointed out this
21 morning, the *Childs* case is somewhat irreconcilable with the
22 other cases we cited.

23 THE COURT: Well, I don't know I would say
24 irreconcilable. It's a different test. There's nothing in
12:03:52 25 the other cases that have rejected *Childs* --

12:03:55 1 MR. NORTH: No.

2 THE COURT: -- they just looked at a different

3 requirement, which is verification.

4 MR. NORTH: Right.

12:04:00 5 THE COURT: And I'm sure plaintiffs would argue the

6 testimony shows that Bard does whatever it can to verify.

7 MR. NORTH: Right.

8 THE COURT: It can't be sure it's got it completely

9 right, but it does what it can to verify.

12:04:12 10 Okay. I just want to have those in mind as I look at

11 the cases over the lunch hour.

12 Okay. We'll see you at 1 o'clock.

13 (End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 17th day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter